

FINDING OF NO SIGNIFICANT IMPACT

1. PROPOSED ACTION: Because of the current threat of biological warfare and its continuing proliferation, there is an urgent need to protect our fighting men and women. The proposed action (preferred alternative) and subject of this final environmental assessment (FEA) is expansion of anthrax vaccine production capabilities through the renovation of anthrax vaccine production and testing facilities located at the Michigan Biologic Products Institute (MBPI) (formerly the Biologic Products Division of the Michigan Department of Public Health). The Joint Vaccine Acquisition Project Management Office (JVAP PMO) manages vaccine development, production, and acquisition for the Department of Defense (DoD). The JVAP PMO contracts with MBPI to purchase anthrax vaccine for the DoD.

The primary objective of the proposed action is to produce sufficient quantities of U.S. Food and Drug Administration (FDA) licensed anthrax vaccine to implement U.S. government policy for protecting its armed forces against death and disease resulting from biological warfare agents such as anthrax. The MBPI is the only establishment licensed by the FDA for the production of anthrax vaccine.

2. ALTERNATIVES CONSIDERED: During the preparation of this FEA, two alternatives in addition to the proposed action were identified. The alternatives identified included meeting the need for increased anthrax vaccine production through a source other than MBPI (Alternative II), and continuing current anthrax vaccine production and testing activities at MBPI in existing facilities in their present size and scope (Alternative III - the no-action alternative).


3. ENVIRONMENTAL CONSEQUENCES AND MITIGATION MEASURES:

Significant adverse environmental impacts are unlikely to result from implementation of the proposed action. The preferred alternative involves conducting increased vaccine production and testing activities at facilities by an experienced workforce already engaged in the conduct of identical activities. These activities involve the use of work practice and engineering controls and adherence to existing regulations and guidance which minimize potential risk to the workforce and the general public.

4. FACTORS CONSIDERED IN THE FINDING OF NO SIGNIFICANT IMPACT: The FEA systematically reviews the nature of the proposed action and associated risks and issues. Particular attention is given to protection of the workforce and the surrounding community as well as associated risks. Reasonable alternatives with regard to needs of the United States and the U.S. Army and potential adverse effects on the environment are evaluated.

5. CONCLUSIONS: The principal conclusion of this FEA is that implementing the proposed action (Alternative I, the preferred alternative) is unlikely to result in significant adverse environmental impacts. Implementation of the proposed action will ensure that an adequate supply of anthrax vaccine is available to fully implement biological defense immunization.

policies. Although implementation of Alternatives II or III will unlikely result in significant adverse environmental impacts, neither of these alternatives adequately address the needs of the national defense.


JOHN C. DOESBURG
Brigadier General, U.S. Army
Joint Program Manager
for Biological Defense

Comments on this Finding of No Significant Impact may be directed to Department of the Army, JOINT VACCINE ACQUISITION PROJECT MANAGEMENT OFFICE, JVAP PMO (ATTN: MR. BRUCE KAY), 568 DOUGHTEN DRIVE, SUITE 100, FORT DETRICK, MD 21702-5040 and must be received by February 3, 1998. Copies of the FEA are available for review by the public at the Ingham County Library, 4538 Elizabeth Rd., Lansing, MI 48917; Lansing Public Library, 401 South Capitol Avenue, Lansing, MI 48933-2037; and the Library of Michigan, 717 Allegan, P.O. Box 30007, Lansing, MI 48909.



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
JOINT PROGRAM OFFICE
FOR BIOLOGICAL DEFENSE
5201 Leesburg Pike
Skyline #3, Suite 1200
Falls Church, VA 22041-3203



MICHIGAN BIOLOGIC PRODUCTS INSTITUTE
ENVIRONMENTAL ASSESSMENT

January 1998

Prepared by:
Joint Program Office for Biological Defense (JPO BD)

Reviewed by:

ROBERT J. CARTON, PH.D.
Environmental Officer
U.S. Army Medical Research
and Materiel Command

ROSS LeCLAIRE, LTC, VC
Contracting Officer Representative
U.S. Army Medical Research and
Materiel Command

Approved by:

ROBERT S. BOROWSKI, LTC, MS
Deputy Program Manager
for Medical Systems
JPO-BD

**RENOVATION OF FACILITIES AND INCREASED ANTHRAX VACCINE PRODUCTION
AND TESTING
AT THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE
FINAL ENVIRONMENTAL ASSESSMENT**

**Prepared by:
Joint Program Office for Biological Defense (JPO BD)
5201 Leesburg Pike
Suite 1200
Falls Church, VA 22041-3203**

**With technical assistance from:
BSA Environmental Services, Inc.
Beachwood, OH 44122**

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Frederick, MD 21703**

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EXECUTIVE SUMMARY

The proposed action (Alternative I) of this Environmental Assessment (EA) is expansion of anthrax vaccine production capabilities at the Michigan Biologic Products Institute (MBPI). This involves renovating Building 12 and expanding Building 16.

The Joint Program Office for Biological Defense (JPO BD) manages Department of Defense (DoD) vaccine development, production, and acquisition. Anthrax has been determined to be a potential biological warfare (BW) threat agent by the DoD. At risk U.S. armed forces can be immunized with the licensed anthrax vaccine to protect them against this BW agent. JPO BD contracts with MBPI, through the U.S. Army Medical Research Acquisition Activity (USAMRAA), to purchase anthrax vaccine for the DoD. As the only U.S. Food and Drug Administration (FDA) licensed establishment for the production of anthrax vaccine, it is necessary that MBPI increase anthrax vaccine production capacity to meet national defense needs.

Two alternatives to the proposed action have been identified: (1) meeting the need for increased anthrax vaccine production through a source other than MBPI (Alternative II); and (2) continue current MBPI anthrax vaccine production and testing activities in existing facilities in their present size and scope (Alternative III, No Action). This EA characterizes the probable and possible environmental impacts, including impacts to human health, that might result from implementation of the proposed action and the alternatives considered.

This EA was prepared in accordance with guidance provided in Army Regulation (AR) 200-2, *Environmental Effects of Army Actions*, dated December 23, 1988, implementing the *National Environmental Policy Act* (NEPA) (42 U.S. Code (USC) 4321-4347). Activities associated with the proposed renovations and expansion and operation of MBPI anthrax vaccine production and testing facilities were systematically reviewed. Feasible alternatives with regard to the needs of the U.S. and the Army and potential adverse impacts on the environment were also evaluated.

The principal conclusions of this EA are: (1) risks to the environment and human health and safety associated with implementing the proposed action are extremely small; (2) renovation and expansion of vaccine facilities at MBPI, and increased anthrax vaccine production will have negligible adverse environmental impacts; and therefore, (3) implementation of the proposed action will not result in significant adverse environmental impacts and will result in significant benefits to the national defense posture. Although implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs Through a Source Other Than MBPI) or Alternative III (No Action Alternative) is not likely to cause significant adverse environmental impacts, neither alternative adequately addresses the needs of the national defense.

TABLE OF CONTENTS

EXECUTIVE SUMMARY.....	ii
1.0 PURPOSE AND NEED FOR THE PROPOSED ACTION.....	1-1
1.1 Introduction.....	1-1
1.2 Purpose and Need for the Proposed Action.....	1-1
1.3 Assessment Methodology.....	1-2
1.4 Previous NEPA Documentation.....	1-2
1.5 Public Participation.....	1-2
2.0 DESCRIPTION OF THE PROPOSED ACTION.....	2-1
2.1 Introduction.....	2-1
2.2 MBPI Organization.....	2-1
2.3 Location and Facilities.....	2-3
2.3.1 Proposed Renovations to Building 12.....	2-3
2.3.2 Proposed Renovations to Building 16.....	2-3
2.4 Description of MBPI Anthrax Vaccine Production and Testing Activities.....	2-5
2.4.1 Production and Testing Activities.....	2-5
2.4.2 Proposed Changes to Anthrax Vaccine Production and Testing.....	2-6
2.5 Safety.....	2-6
2.5.1 General Safety.....	2-6
2.5.2 Biological Safety.....	2-7
2.5.2.1 Anthrax Vaccine Production Safety.....	2-8
2.5.2.2 Anthrax Vaccine Potency Testing.....	2-9
2.5.3 Chemical Safety.....	2-10
2.6 Orientation and Training.....	2-11
2.7 Inspections.....	2-11
2.7.1 FDA Inspections.....	2-11
2.7.2 Security Inspections.....	2-13
2.7.3 DA Inspections.....	2-13
2.7.4 Incinerator Inspections.....	2-14
2.7.5 Phase I Environmental Site Assessments.....	2-14
2.8 Occupational Health.....	2-15
2.8.1 Medical Monitoring of Personnel.....	2-15
2.8.2 Medical Monitoring of Vaccine Recipients.....	2-15
2.9 Security.....	2-16
2.10 Waste Stream Management.....	2-17
2.10.1 Wastewater.....	2-17
2.10.2 General Solid Waste.....	2-17
2.10.3 Regulated Medical Waste.....	2-17
2.10.4 Incinerator.....	2-19
2.11 Emergency Procedures.....	2-19
2.11.1 Hazardous Chemicals.....	2-19
2.11.2 Etiologic Agents.....	2-19
2.11.2.1 Accidents Involving Avirulent <i>B. anthracis</i>	2-19
2.11.2.2 Accidents Involving Virulent <i>B. anthracis</i>	2-20
2.11.2.3 Accidents and Incidents.....	2-20
2.11.2.4 Accident Investigation.....	2-20

2.12 Special Considerations.....	2-21
2.13 Animal Care and Use.....	2-21
3.0 ALTERNATIVES	3-1
3.1 Introduction.....	3-1
3.2 Alternatives	3-1
3.2.1 Alternative I - Renovation and Expansion of MBPI Facilities and Increased Anthrax Vaccine Production (Preferred Alternative)	3-1
3.2.2 Alternative II - Meeting Increased Anthrax Vaccine Production Needs through a Source Other Than MBPI	3-1
3.2.3 Alternative III - Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope (No Action Alternative)	3-1
4.0 AFFECTED ENVIRONMENT	4-1
4.1 Introduction.....	4-1
4.2 Location.....	4-1
4.3 Plant and Animal Ecology.....	4-1
4.4 Land Use.....	4-4
4.5 Environmental Justice.....	4-4
4.6 Water Resources.....	4-4
4.6.1 Surface Water.....	4-4
4.6.2 Groundwater	4-5
4.7 Geology.....	4-5
4.8 Historic and Cultural Resources.....	4-6
4.8.1 Historic.....	4-6
4.8.2 Archaeological.....	4-6
4.9 Agriculture	4-6
4.10 Climate.....	4-6
4.11 Energy Resources.....	4-7
4.12 Noise	4-7
4.13 Odors.....	4-7
4.14 Socioeconomic Environment.....	4-7
4.15 Transportation.....	4-8
4.16 Air Quality.....	4-8
4.17 Public Opinion.....	4-8
4.18 Human Populations.....	4-8
5.0 ENVIRONMENTAL AND SOCIOECONOMIC CONSEQUENCES.....	5-1
5.1 Introduction.....	5-1
5.2 Assessment Approach.....	5-1
5.3 Potential Environmental Consequences of the Proposed Action	5-2
5.3.1 Plant and Animal Ecology.....	5-2
5.3.2 Land Use.....	5-2
5.3.3 Environmental Justice.....	5-3
5.3.4 Surface Water.....	5-4
5.3.5 Groundwater	5-5
5.3.6 Geology.....	5-5
5.3.7 Historic and Cultural Resources.....	5-6
5.3.8 Agriculture.....	5-7
5.3.9 Climate.....	5-7
5.3.10 Energy Resources.....	5-7

5.3.11 Noise.....	5-8
5.3.12 Odors.....	5-8
5.3.13 Socioeconomic Environment.....	5-9
5.3.14 Transportation.....	5-9
5.3.15 Air Quality.....	5-9
5.3.16 Public Opinion.....	5-11
5.3.17 Program Benefits.....	5-11
5.3.18 Human Health and Safety.....	5-12
5.3.18.1 Public Health and Safety.....	5-12
5.3.18.2 Worker Health and Safety.....	5-12
5.3.18.3 Health and Safety of Vaccine Recipients.....	5-13
5.3.18.4 Accidents and Incidents.....	5-14
5.3.19 Consequences of Actions Abroad.....	5-14
5.3.20 Environmental Consequences of FDA-Cited Deviations at the MBPI.....	5-14
5.3.21 Cumulative Impacts.....	5-16
5.4 Comparison of the Proposed Action and the Alternatives.....	5-17
5.4.1 Alternative I - Renovation and Expansion of MBPI Facilities and Increased Anthrax Vaccine Production (Preferred Alternative).....	5-23
5.4.2 Alternative II - Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI.....	5-23
5.4.3 Alternative III - Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope (No Action Alternative).....	5-24
6.0 CONCLUSIONS.....	6-1
7.0 REFERENCES.....	7-1
8.0 PERSONS AND AGENCIES CONSULTED.....	8-1
9.0 PREPARERS.....	9-1
10.0 ACRONYMS AND ABBREVIATIONS.....	10-1

LIST OF TABLES

Table 5-1. Environmental Impact Analysis of FDA-Cited Deviations.....	5-15
Table 5-2. Summary of Potential Environmental Impacts Related to Renovation and Expansion Activities at MBPI.....	5-17
Table 5-3. Summary of Potential Environmental Impacts Related to Anthrax Vaccine Production Activities at MBPI.....	5-18
Table 5-4. Comparison of the Potential Environmental Impacts of the Proposed Action and the Alternatives.....	5-21

LIST OF FIGURES

Figure 2-1. Organizational Structure of the Michigan Biologic Products Institute.....	2-2
Figure 2-2. MBPI Campus Map.....	2-4
Figure 4-1. Location of Ingham County, Michigan.....	4-2
Figure 4-2. Location of MBPI (indicated by *) within Lansing, Michigan.....	4-3

APPENDICES

Appendix A. Chemical Inventory for Anthrax Vaccine Production and Testing Activities at MBPI as of February 18, 1997	A-1
Appendix B. City of Lansing Emergency Management	B-1
Appendix C. Ingham County Element List	C-1
Appendix D. Recipients of the EA	D-1
Appendix E. Newspaper Draft Notice of Availability	E-1

1.0 PURPOSE AND NEED FOR THE PROPOSED ACTION

1.1 INTRODUCTION

The proposed action and subject of this environmental assessment (EA) is expansion of anthrax vaccine production capabilities through the renovation of anthrax vaccine production and testing facilities located at MBPI (formerly the Biologic Products Division of the Michigan Department of Public Health (MDPH)). The proposed action entails renovations to Building 12 and expansion of Building 16. The renovation and expansion activities are necessary to increase production capabilities for the anthrax vaccine. A full description of the proposed action is located in Section 2.0.

This EA has been prepared in accordance with NEPA (42 USC 4321-4347) which requires federal agencies to give adequate consideration to potential environmental impacts associated with their proposed major actions. In addition, NEPA requires that the interested and affected public be informed of the environmental analyses performed. The Council on Environmental Quality (CEQ), Executive Office of the President, has promulgated regulations implementing NEPA (40 Code of Federal Regulations (CFR) 1500-1508). Army Regulation (AR) 200-2, *Environmental Effects of Army Actions*, dated December 23, 1988 (32 CFR 651), is the Department of the Army's (DA) implementation of NEPA and CEQ regulations. AR 200-2 requires the DA to prepare environmental documentation in the form of an EA to determine the extent of environmental impacts of a proposed project and decide whether or not those impacts are significant. Projects requiring the preparation of an EA include alteration of a laboratory that will use hazardous chemicals, drugs, or biological or radioactive materials [AR 200-2, paragraph 5-3(g)].

1.2 PURPOSE AND NEED FOR THE PROPOSED ACTION

In a memorandum dated August 26, 1991, the Deputy Secretary of Defense identified biological defense as a high priority requirement. The Joint Chiefs of Staff (JCS) articulated the importance of medical biological defense products to military readiness in its Mission Needs Statement for Biological Defense dated August 31, 1992. This document established an urgent need for creating vaccine production and stockpile capability. As a result, the Joint Program Office for Biological Defense (JPO BD) was established. The JPO BD manages DoD vaccine development, production, and acquisition for which the DA is the lead agency.

The DoD has determined that *Bacillus anthracis* (*B. anthracis*), the causative agent of anthrax is a potential biological warfare agent. In response to the need for biological defense vaccines, the DA contracts with MBPI through the U.S. Army Medical Research Acquisition Activity (USAMRAA) to purchase anthrax vaccine. The MBPI is the only establishment licensed by the Food and Drug Administration (FDA) for the production of anthrax vaccine. This vaccine is currently the only FDA-licensed vaccine for protection against anthrax. The renovation and expansion of FDA-licensed anthrax vaccine production capabilities are required to provide DoD with the flexibility to fully implement its biological defense immunization policies.

1.3 ASSESSMENT METHODOLOGY

The EA describes and characterizes the activities associated with implementing the proposed action (renovations, expansion, and operations) (see Section 2.0). Alternatives to the proposed action are examined with regard to the needs and mission of the DA (see Section 3.0). This EA then discusses the components of the environment that might be potentially affected by the proposed action (see Section 4.0) and analyzes the potential impacts of the proposed action and identified alternatives for their potential environmental consequences including consequences to human health (see Section 5.0). This analysis also considers impacts that are expected to result after several years, in conjunction with other activities in the area, or as a result of an accident or incident.

1.4 PREVIOUS NEPA DOCUMENTATION

Vaccine production and testing activities of the MBPI were previously analyzed for potential environmental impact in accordance with NEPA and AR 200-2. The *Anthrax Vaccine Production and Testing at the Michigan Department of Public Health EA* (MDPH EA) (U.S. Army Medical Research and Development Command (USAMRDC), 1993a) resulted in a Finding of No Significant Impact (FNSI).

The biological defense biomedical and microbiology activities used in vaccine production, which are similar or identical to the proposed action, were previously examined for environmental impact in several documents including the *Biological Defense Research Program Final Programmatic Environmental Impact Statement* (BDRP FPEIS) (DA, 1989) and site-specific EAs. In addition, the implementation of the JPO BD Joint Vaccine Acquisition Program (JVAP) was evaluated in the *JVAP Draft Programmatic EA* (JVAP PEA) (JPO BD, 1997). In these documents, standards for evaluating potential environmental impacts were established. Because of the similarities between the proposed action of this EA and previously examined biological defense activities, these standards were considered and applied where appropriate in this EA. This approach entails referencing and summarizing specific analyses, discussions, and conclusions of those documents without providing detailed discussions in the present EA (see Section 5.2).

1.5 PUBLIC PARTICIPATION

A draft of the EA was distributed to the public, private sector and government entities, including elected officials, identified as having possible interest in the proposed action (see Appendix D). A notice published in the Lansing Journal on November 20-22, 1997 announced availability of the draft EA and solicited comments during a public comment period ending on December 20, 1997 (see Appendix E). The draft EA was also made available for review in selected public libraries. Finally, the draft EA and the NEPA documents it referenced were made available electronically on the world wide web at:
<http://www.armymedicine.army.mil/jvap-mbpi.dea>.

The public was encouraged to review and comment on this draft EA. No comments were received.

The final EA and the resulting Finding of No Significant Impact (FNSI) will be released for public review and comment. Electronic copies of this document, the FNSI, and documents referenced in the final EA will be made available on the world wide web at:
<http://www.armymedicine.army.mil/jvap-mbpi.fea>.

2.0 DESCRIPTION OF THE PROPOSED ACTION

2.1 INTRODUCTION

The DoD has determined that biological defense vaccines are necessary to protect service men and women assigned to high-threat areas and that all such vaccines should be licensed by the FDA (DoD Directive (DoDD) 6205.3, *DoD Immunization Program for Biological Warfare Defense*). In this regard, the acquisition and stockpile of anthrax vaccine are necessary to ensure the ability of the DoD to immunize military personnel as needed. Anthrax Vaccine Adsorbed (AVA) is an FDA-licensed product which has been manufactured by MBPI since 1970. The MBPI is the only facility licensed by the FDA for production of anthrax vaccine. The DA began contracting with MDPH in 1988 for the purchase of anthrax vaccine and has since supported efforts to gradually increase the anthrax vaccine production capacity of MDPH (and now, MBPI) to ensure that there are adequate quantities available to immunize troops as necessary.

The proposed action is the renovation of two existing MBPI anthrax vaccine production facilities (Buildings 12 and 16) and involves expanding Building 16 to accommodate increased anthrax vaccine production.

2.2 MBPI ORGANIZATION

The MBPI was formerly the Biologic Products Division of the MDPH. The MDPH is the lead agency for the State of Michigan for developing health policy and planning, implementing and assessing programs related to health care issues, health care delivery, and health education. As part of its earlier mission, MDPH produced several biological products including vaccines, under FDA licensure, since 1955. Michigan Executive Order (EO) 1995-25 created the MBPI as a temporary (2-year) agency, which would ultimately be transferred from State ownership to the private sector. EO 1995-25 removed the Biologic Products Division from MDPH and transferred all of its functions, responsibilities, contractual obligations, property, and employees to the MBPI.

Until privatization becomes final in 1997, MBPI operates under interdepartmental agreements with MDPH and must adhere to MDPH rules, regulations, and procedures (Nummy, 1997a). In this regard, MBPI activities are conducted under the oversight and control of the applicable MDPH offices such as the Health and Safety Office and the Security Office. The MDPH and MBPI will operate under these agreements until privatization is complete and the separation of the two facilities becomes finalized.

The current MBPI Responsible Head of biologic products manufacturing also serves as the Director of the MBPI and reports to a three-member Commission appointed by the Governor of Michigan (see Figure 2-1). The Commission provides supervision, policy control, and direction to MBPI. The MBPI Director supervises employees, administers the Pharmaceutical Products Fund, and manages operation of the facilities.

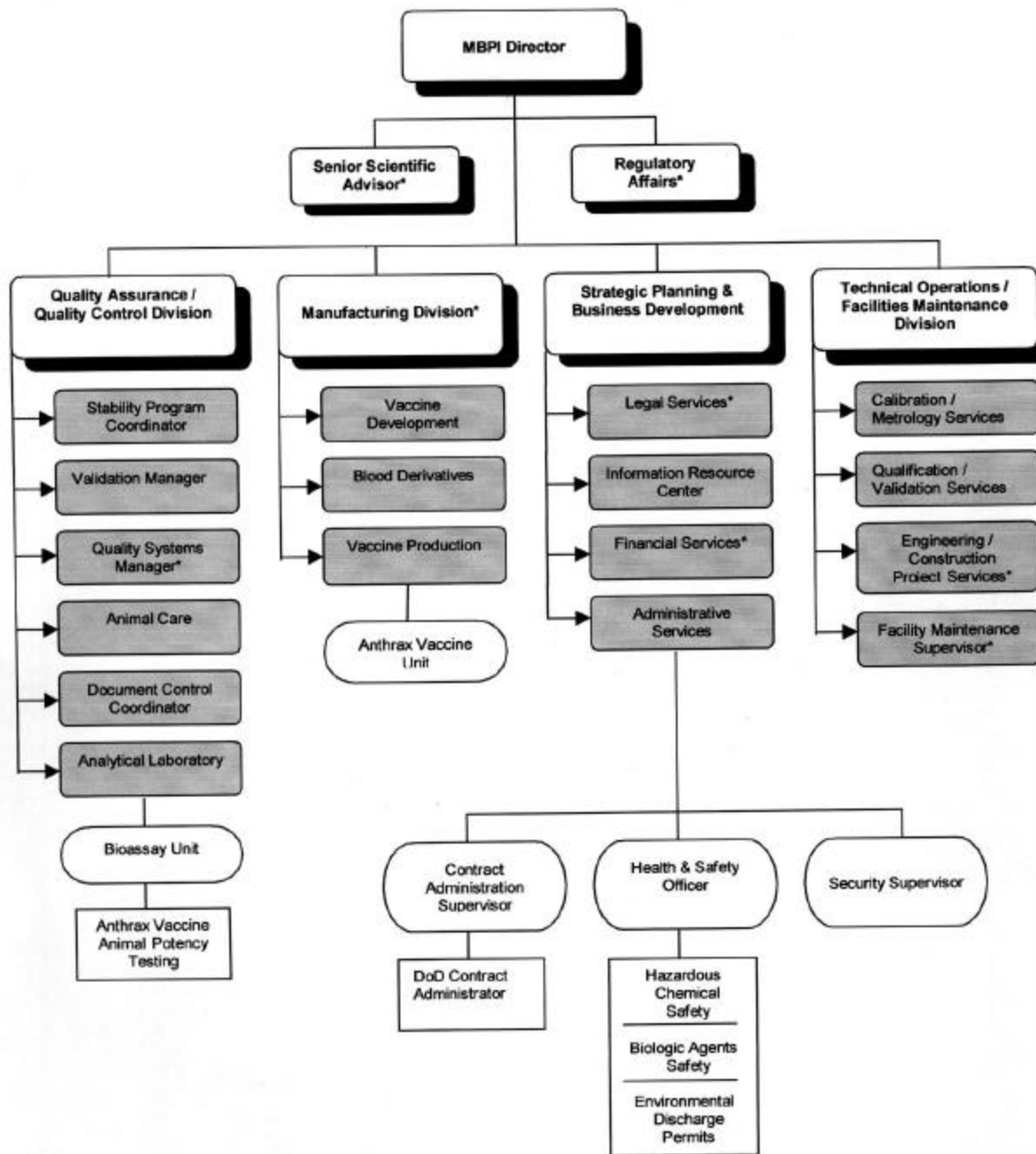


Figure 2-1 Michigan Biologic Products Institute Organizational Chart
(Relevant areas of MBPI organization are shown above.)

* Indicates a new position

2.3 LOCATION AND FACILITIES

The MBPI is located on North Martin Luther King, Jr. Boulevard (formerly North Logan Street) on the north side of the city of Lansing. For additional information regarding the geographical location of MBPI, see Section 4.2. The campus contains a total of 25 buildings. Five buildings (Buildings 12, 16, 31, 32, and 45) house activities involved in anthrax vaccine production and testing (see Figure 2-2). Fermentation, purification, adsorption, storage of sublots, and the vaccination of guinea pigs take place in Building 12. Formulation and storage of the final product, filling, and packaging take place in Building 16. Guinea pigs used for testing anthrax vaccine are bred and maintained in Building 31. Anthrax vaccine potency testing is conducted in Building 45. Building 32 contains the heating and distribution plant.

The MBPI is proposing to modify existing anthrax vaccine production, storage, and testing facilities located in Buildings 12 and 16 on the MBPI campus. Proposed renovations include modifications to building infrastructure as well as expanding Building 16.

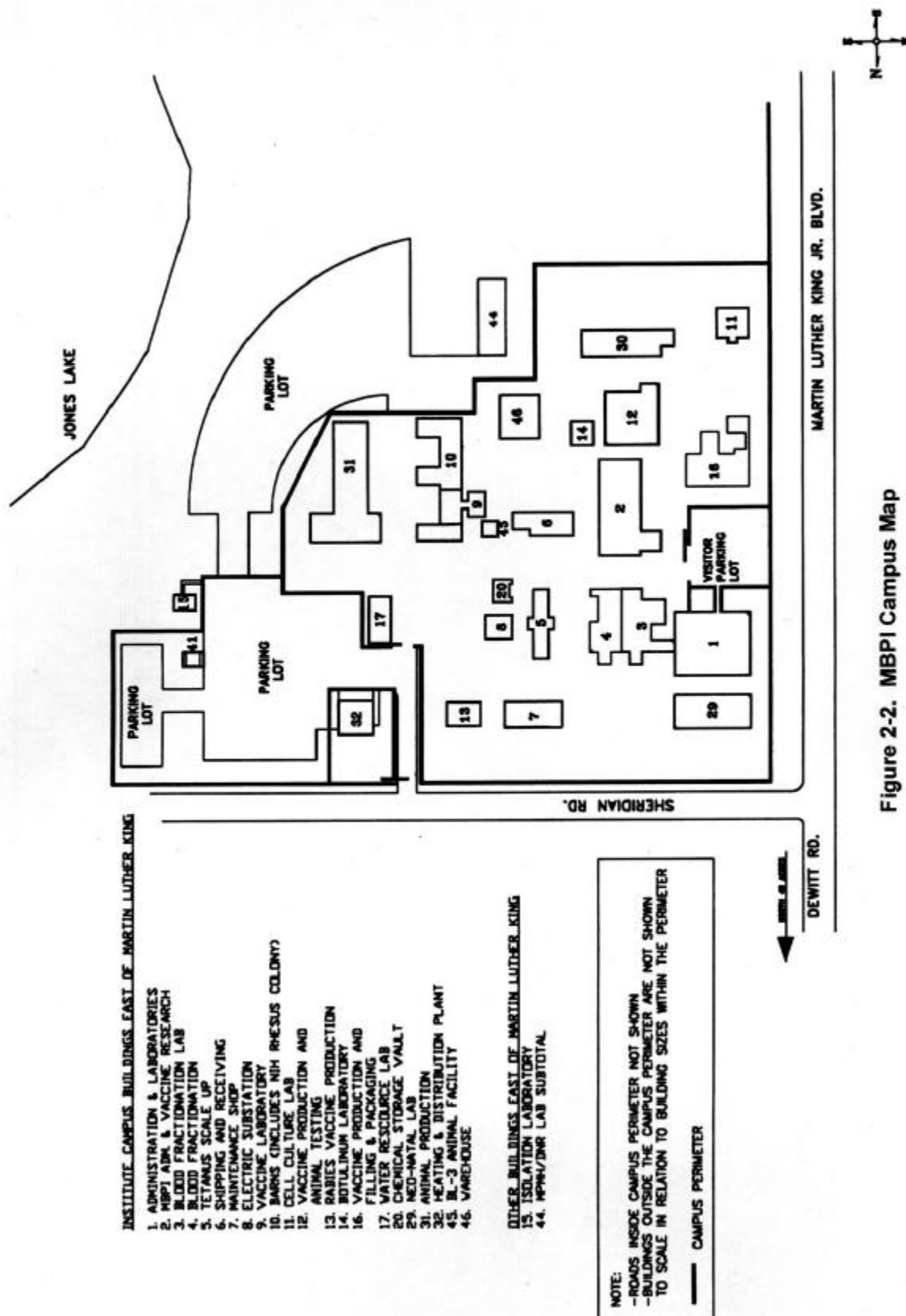
2.3.1 Proposed Renovations to Building 12

The proposed action entails infrastructural renovation to Building 12, the site where anthrax vaccine is produced. These renovations are required to enhance the production capacity of the facility and to meet the regulatory requirements of the FDA. Anthrax vaccine production activities are discussed in Section 2.4.1. Building 12 facilities will be renovated to provide special utilities for supplying water suitable for injection, clean steam, and clean compressed air. A room will be added to the first floor of Building 12 for storing the special utilities equipment.

Building 12 also contains animal facilities (Rooms 105, 106, 107, 108, and 109) in which groups of guinea pigs are housed prior to vaccine testing (see Section 2.4.1). The renovations proposed for the Building 12 animal facility include replacement of heating, ventilation, and air conditioning (HVAC) components. The proposed renovations also include the addition of passageways and rooms necessary to achieve the required segregation of animals, experimental procedures, personnel entry/exit, clothing change, and cage washing. These renovations are necessary to comply with FDA and U.S. Department of Agriculture (USDA) regulations and Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) guidelines.

2.3.2 Proposed Renovations to Building 16

The formulation and storage of final product (AVA), and the filling and packaging of containers take place in Building 16. Improvements proposed to the third floor of Building 16 (filling and packaging area) include the installation and qualification (test for compliance with existing standards) of the HVAC system that will supply high efficiency particulate air (HEPA) filtered to ancillary support spaces such as the vial and stopper wash area. Other improvements include renovations to work area design features such as partitions, doors, walls, floors, and ceilings.



Additional improvements proposed for Building 16 include the renovation of cold rooms located in the basement. MBPI proposes to divide cold room 3 into three separate rooms and to upgrade cold room 4. It also proposes creating two additional cold rooms (rooms 8 and 9). These cold room renovations will include installing redundant refrigeration equipment (back-up systems).

The MBPI also proposes renovating the aseptic manufacturing space located on the first floor of Building 16. Renovations to this space will segregate activities associated with manufacturing, aseptic blending, and bulk vaccine preparation. These changes will create space for the movement of materials and personnel into and out of the space; segregation, preparation, and storage of clean and soiled materials and equipment; and optimize the use of space for personnel, material, and product.

The MBPI also proposes to create additional anthrax vaccine facilities by expanding the north side of Building 16. This expansion will create an 8,800 square foot, one-story, brick addition with a mezzanine level (i.e., balcony). This facility will be used in the production and purification of anthrax vaccine as well as for temporary storage of bulk vaccine and in-process testing (Fine, 1997).

2.4 DESCRIPTION OF MBPI ANTHRAX VACCINE PRODUCTION AND TESTING ACTIVITIES

The MBPI produces anthrax vaccine for the DoD as well as for a small number of other customers. In addition to anthrax vaccine, MBPI produces or blends vaccines for tetanus, diphtheria, pertussis, botulism (*Clostridium botulinum* type B, for veterinary use), and rabies. MBPI also produces other biologics such as albumin and immune globulin.

2.4.1 Production and Testing Activities

Anthrax vaccine is produced from an avirulent strain (one which is not capable of causing disease) of *B. anthracis*. The production of anthrax vaccine involves growing the avirulent, nonproteolytic strain of *B. anthracis* in a fermentor, partially purifying and processing the culture material, sterilizing, labeling, and bottling the final product. Anthrax vaccine production requires techniques and controls to maintain production integrity, assure a safe and effective product, and to protect the laboratory worker from related hazards. The activities conducted in Building 12 (rooms 204, 206, 207, and 209) require biosafety level (BL) 2 containment and the vaccination of workers (see Section 2.5.2 for a description of BLs; see Section 2.8.1 for discussion of worker health and safety). Information regarding the safety practices and procedures used in the production of anthrax vaccine is located in Section 2.5.2.1.

Once anthrax vaccine is produced it undergoes stability, sterility, purity, and potency testing. Potency testing is conducted on each lot of anthrax vaccine to ensure effectiveness in preventing anthrax. Potency testing is also periodically conducted on stored vaccine. Potency testing is accomplished by immunizing a laboratory animal (i.e., guinea pig) with the vaccine and then exposing it to a virulent (disease-producing) strain of anthrax. The guinea pigs used in potency testing are housed in the Building 12 animal facility until transfer to the BL-3 animal facility (Building 45) where they undergo challenge. Increased safety and containment procedures must be used for potency testing to minimize hazards to laboratory workers who administer the challenge dose of virulent *B. anthracis*, and who maintain the challenged

experimental animals. Information regarding safety practices and procedures required for anthrax vaccine testing is located in Section 2.5.1.

2.4.2 Proposed Changes to Anthrax Vaccine Production and Testing

The proposed renovation and expansion of MBPI facilities are intended to maintain the capability of MBPI to continue to produce anthrax vaccine in sufficient quantities to meet military needs (as determined by the DoD), and in accordance with FDA requirements. The MBPI currently uses four fermentors for producing anthrax vaccine. An additional fermentor serves as a backup. Implementation of the proposed action will result in an additional eight fermentors. It is anticipated that six fermentors will be used routinely, and the others reserved for use when one or more fermentors are not operational or to accommodate increased demand (Burgoyne, 1997).

It is anticipated that after the proposed renovations have been completed, anthrax vaccine production capacity at MBPI will increase three-fold. While implementing the proposed action will increase anthrax vaccine production capacity at the MBPI, the manner (qualitative aspects) in which anthrax vaccine is produced and tested will not change.

2.5 SAFETY

The procedures by which anthrax vaccine is produced and tested at the MBPI are described in the following sections. Descriptions of safety, security, waste handling and disposal, and emergency procedures are included in these discussions.

2.5.1 General Safety

Terms of the agreement between the DoD and MBPI for the production and testing of anthrax vaccine require that MBPI work conform to certain standards and adhere to certain regulations. These include the guidelines published by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) (see Section 2.5.2); FDA regulations including current Good Manufacturing Practices (cGMP) regulations (21 CFR 211 and amendments) and Good Laboratory Practices (GLP) regulations (21 CFR 58); and 32 CFR 626, *Biological Defense Safety Program*. MBPI must comply with all applicable federal and state laws, codes, ordinances, and regulations (including obtaining required licenses and permits) which relate to their operations.

The anthrax vaccine production and testing activities at MBPI are conducted according to various written plans detailing procedures for instituting and maintaining a safe work place. Currently, the MBPI relies upon materials prepared by the MDPH and under which their work was conducted prior to the privatization process. As the privatization process proceeds, MBPI will prepare and distribute their own safety and procedural documents as federal, state, local, and DA rules require. Among the guidelines in use by MBPI is the MDPH Safety and Health Program, which implements all applicable federal and state regulations. The procedures detailed in this program include safety management and responsibilities, personnel training, the use of personal protective equipment and clothing, waste handling procedures, inspections, hazard communications, laboratory training, spill and emergency procedures, and numerous other program elements (MDPH, 1992a).

2.5.2 Biological Safety

The production and testing of anthrax vaccine necessitate the use and handling of etiologic agents (e.g., bacteria) with the potential to cause disease. The CDC and the NIH have developed guidelines (*Biosafety in Microbiological and Biomedical Laboratories* (CDC/NIH, 1993)) that describe various combinations of laboratory practices and engineering controls for containing the potential hazards associated with the use of etiologic agents. CDC/NIH Guidelines describe the four BLs recommended for laboratory operations with certain infectious agents and/or their toxins. Animal biosafety levels (ABLs) describe the combinations of work practices and engineering controls for work with vertebrate animals (e.g., guinea pigs) infected or potentially infected with agents assigned to corresponding BL designations.

Under CDC/NIH Guidelines, the laboratory director determines the appropriate biosafety level based upon “the virulence, pathogenicity, biological stability, route of spread, and communicability of the agent; the nature or function of the laboratory; the procedures and manipulations involving the agent; the endemicity of the agent; and the availability of effective vaccines or therapeutic measures” (CDC/NIH, 1993). The CDC/NIH Guidelines include agent summary statements that provide guidance for selecting appropriate BLs as well as specific information about laboratory hazards associated with various agents (CDC/NIH, 1993).

In assigning a BL, the laboratory director takes into consideration such factors as the volume and concentration of an agent as well as activities which by their nature may be intrinsically more hazardous (e.g., manipulations likely to introduce etiologic agents into the air). Similarly, the laboratory director takes into account the significance of the quantity of etiologic agent involved. Certain activities, such as the production of vaccine, require larger quantities of a microorganism that must be considered in the development of work practice and engineering control guidelines.

Anthrax vaccine production and testing at the MBPI involve the use of BL-2 and BL-3 containment practices. BL-2 practices, safety equipment, and facilities are appropriate for performing work with the broad spectrum of indigenous (native) moderate-risk agents present in the community and associated with human disease of varying severity. Work with indigenous or exotic agents that have serious or lethal consequences if inhaled requires BL-3 containment (CDC/NIH, 1993). All MBPI BL-3 and ABL-3 containment facilities associated with anthrax vaccine testing are located in Building 45, a facility specifically designed and constructed for its current use (USAMRDC, 1993a).

All work with *B. anthracis* at the MBPI must be conducted in accordance with CDC/NIH Guidelines (CDC/NIH, 1993), 32 CFR 626, DA Pamphlet (Pam) 385-69, FDA regulations, the MDPH Bureau of Laboratory and Epidemiological Services Biosafety Program (MDPH, 1992b), and the procedural manuals and standard operating procedures (SOPs) for the manufacture of anthrax vaccine that have been approved and accepted by the FDA. These guidelines and manuals prescribe all aspects of handling potentially infectious materials during the entire process of vaccine production and testing. A written inventory of *B. anthracis* must be maintained and the locations of all containers tracked (MDPH, 1992b).

2.5.2.1 Anthrax Vaccine Production Safety

The production of anthrax vaccine takes place in rooms 204, 206, 207, and 209 in MBPI Building 12. The MBPI laboratories engaged in the production of anthrax vaccine meet or exceed BL-2 containment practices and must be exclusively dedicated to the production of anthrax vaccine. While production work is in progress, access to these BL-2 laboratories must be restricted to those individuals who have been immunized against anthrax.

Anthrax vaccine production involves the use of an avirulent, nonproteolytic, non-encapsulated strain of *B. anthracis*. The avirulence of the anthrax spores is verified prior to preparing anthrax vaccine by growing them on special media in the presence of carbon dioxide. The colonies which result have distinguishing physical characteristics; colonies lacking these characteristics are not used (MDPH, 1993).

A seed culture (10 liters) of the avirulent anthrax strain is prepared from the cultured avirulent spores and used to inoculate 100 liters of growth medium in a fermentor. Following a period of growth, the vaccine is then prepared by adsorbing the protective component of the organism onto an aluminum hydroxide gel. The adsorbed gel is then centrifuged, resuspended in saline, and treated with preservative (benzethonium chloride, 1:40,000 final concentration) and stabilizer (formaldehyde, 0.009 percent final concentration). The resultant vaccine is then tested for sterility, chemical purity, and potency (effectiveness in preventing anthrax) (MDPH, 1993).

Biological safety cabinets equipped with HEPA filtration are incorporated into vaccine production activities to maintain a sterile environment and the purity of the cultures. HEPA filtration removes 99.97 percent of particulate matter greater than or equal to 0.3 micrometers. In addition, the exhaust air from biological safety cabinets undergoes HEPA filtration prior to exhausting to the outside. All air exhausted from BL-2 rooms involved in anthrax vaccine production is HEPA-filtered. Gauge readings from biological safety cabinets must be recorded daily and airflow measurements must be validated annually. Used cabinet filters must be decontaminated in place with paraformaldehyde gas, removed, steam sterilized and placed in a dumpster for disposal. Cultures of laboratory surfaces in the anthrax vaccine production facility are monitored bi-weekly for contamination to validate the effectiveness of laboratory containment practices (Nummy, 1997b).

The CDC/NIH Guidelines provide Agent Summary Statements for several etiologic agents including anthrax. These statements are generic and are individualized by laboratory supervisors to address the risks associated with operations. At the MBPI, anthrax vaccine production activities use an avirulent strain of *B. anthracis* and employ BL-2 containment. Potency testing activities require small quantities of virulent *B. anthracis* and employ BL-3 containment. In the context of the BL-3 work performed at the MBPI, the CDC/NIH Guidelines recommend that air exhausted from biological safety cabinets be filtered through HEPA filters. At MBPI, all exhaust air (biological safety cabinets and laboratory air) is HEPA-filtered as an added precaution (Nummy, 1997b).

The MDPH Bureau of Laboratory and Epidemiological Services Biosafety Program and 32 CFR 626 describe the principles and practices of biosafety and the minimum practices required for the operation of BL-2 and BL-3 activities at the MBPI. The guidelines for maintaining BL-2 or BL-3 containment must be posted in each laboratory and biohazard signs must be used to

identify the nature of laboratory biohazards, laboratory point of contact, and restrictions to entry (e.g., required immunizations) (MDPH, 1992b; Davis, 1997a).

2.5.2.2 Anthrax Vaccine Potency Testing

Potency testing must be conducted on given quantities of newly produced vaccine and periodically on stored vaccine. Various concentrations of anthrax vaccine are injected into guinea pigs followed by a challenge dose of virulent anthrax administered by injection 14 days later. Vaccine potency must be confirmed according to FDA regulations to maintain product licensure (21 CFR 620.3). A master culture of *B. anthracis* obtained from Fort Detrick is used to challenge immunized guinea pigs. Virulent cultures of *B. anthracis* are not grown or prepared at MBPI (Nummy, 1997b).

All work with virulent anthrax, including the challenge of guinea pigs for potency testing, must be conducted within biological safety cabinets using BL-3 containment (Building 45). All of the air exhausted from biological safety cabinets and animal cages and all air exhausted from the building must pass through HEPA filters. All activities conducted with virulent *B. anthracis* and all animal injections must be conducted in a manner that minimizes the release of microbial aerosols. Numerous additional requirements are associated with vaccine potency testing including the necessary presence of two people; adherence to decontamination protocols; and the use and sterilization of personnel protective equipment such as autoclavable shirts and pants, long sleeve surgical gowns, surgical gloves, head covers, plastic boots, safety goggles, and respirators (MDPH, 1993).

Solutions of the material used to conduct potency testing contain 6.8×10^7 spores per milliliter (ML) of *B. anthracis*, Vollum strain. This is a 1:100 dilution of the master concentrate (6.8×10^9 spores per ML). A 100-fold dilution of the challenge suspension is made (6.8×10^5 spores per ML) and then further diluted to yield a solution containing 10^4 spores per ML. A portion of this diluted spore suspension is used to challenge the guinea pigs and a portion is used to incubate microbiological plates for colony counting (10 spores per ML) (MDPH, 1993). All dilutions and injection activities involving *B. anthracis* take place in biological safety cabinets in Building 45.

Guinea pigs receive a 0.1 ML subcutaneous injection of the diluted spore suspension. Written protocols for this operation describe the actions required to minimize the potential for aerosol production, self-injection, and laboratory contamination. Following guinea pig injection, petri dishes containing spore suspension and nutrient agar are prepared and incubated. The number of colonies that grow indicate the number of spores that each guinea pig received (MDPH, 1993).

The animals used for potency testing must remain in cages and all materials (including gowns and gloves) must be removed and placed into an autoclave (steam sterilization). Non-autoclavable items such as the respirators and goggles must be decontaminated in bleach. All materials removed from the animal room must be heat sterilized by autoclave for 2 hours. Sterility indicators are required for each autoclave run (MDPH, 1993).

During the 10-day period of animal observations, personnel must gown and glove, step into the bleach foot bath upon exiting the room, and autoclave all materials which are removed.

Leather gloves are required when handling guinea pigs. Dead guinea pigs are placed into doubled orange biohazard-labeled, plastic bags. Guinea pig carcasses are incinerated daily (see Section 2.10.5) (MDPH, 1993).

2.5.3 Chemical Safety

All MBPI operations involving the use, handling, storage, and disposal of chemicals, hazardous materials, and hazardous waste are governed by the policies and procedures of the MDPH Chemical Hygiene Plan (CHP) (MDPH, 1992c). Operations requiring the use of hazardous chemicals must comply with federal hazardous waste regulations (40 CFR 260-266), Department of Transportation (DOT) Hazardous Materials Regulations (49 CFR 171), the Michigan Hazardous Waste Management Act, and federal (29 CFR 1910) and state (Michigan Occupational Safety and Health Act (MIOSHA)) regulations governing the occupational exposure to hazardous materials. A list of the chemicals used in the production of anthrax vaccine is located at Appendix A.

Operations at MBPI must adhere to requirements of the Hazard Communications Standard (29 CFR 1910.1200), the Occupational Safety and Health Administration (OSHA) Laboratory Standard (29 CFR 1910.1450), and state regulations (Michigan Act 154 of the Public Acts of 1974, MIOSHA, as amended), which describe the receipt, distribution, and use of Material Safety Data Sheets (MSDS), through implementation of MDPH Procedure Number 3010.1 (MDPH, 1987a). MSDSs received from chemical manufacturers or suppliers must be distributed to the chemical user and an up-to-date list of all chemicals in use at the MBPI must be maintained and distributed. MSDSs for chemicals used in MBPI laboratories must be kept in notebooks in each laboratory. Information regarding the receipt of a new or revised MSDS must be posted.

Each laboratory within the MBPI is required to maintain its own CHP which addresses specific chemical hazards. Each laboratory must designate a chemical hygiene officer (CHO) who is responsible for implementing the details of the CHP, and ensuring that laboratory employees and supervisors receive annual training and training for all unique hazards.

In accordance with 29 CFR 1910.1045 (Hazard Communication) and MIOSHA Rule 325.70101, all employees handling hazardous chemicals must be trained and knowledgeable regarding the chemicals that they use. The chemical health and safety information that must be available to MBPI personnel includes the content of the OSHA (and also MIOSHA) Laboratory Standard and appendices, the location and availability of the CHP, Permissible Exposure Limits (PELs) for OSHA-regulated substances, the location of MSDSs, and the physical and health hazards of the chemicals that the worker will be using.

In accordance with 40 CFR 261.5, the MDPH qualifies as a small generator of hazardous waste and is registered with the U.S. Environmental Protection Agency (USEPA). Michigan law allows the issuance of a single hazardous waste permit to state agencies sharing the same street address. The hazardous waste permit for the MDPH and the MBPI is held in the name of the Michigan Department of Environmental Quality (DEQ) (EPA generator number MID 981778806) (Brown, 1997). Anthrax vaccine production and testing activities conducted at the MBPI generate less than 10 pounds per year of hazardous wastes (Nummy, 1997c).

2.6 ORIENTATION AND TRAINING

The MDPH Health and Safety Program and the MDPH Bureau of Laboratory Epidemiological Services Biosafety Program must be made available to all MBPI personnel. Personnel having potential exposure to infectious materials must receive initial and annual training. Additional training is required following modification to tasks or procedures that may affect occupational exposure.

MBPI personnel working with hazardous chemicals or infectious agents, or having the potential for exposure to chemicals must receive relevant initial and annual safety training. Safety orientation for employees working with hazardous chemicals includes review of operations in work areas where hazardous chemicals are present, the location of hazardous chemical inventories and the MSDSs, methods of detecting the presence or release of hazardous chemicals, physical and health hazards of chemicals in their work area, methods of self-protection, and details of the Hazard Communication program. Certificates of training are issued following required training (MDPH, 1987a).

2.7 INSPECTIONS

Specific phases of MBPI operations are inspected at periodic intervals by various federal, DoD, DA, and Michigan agencies.

2.7.1 FDA Inspections

The development, testing, and production of vaccines are regulated and enforced by the U.S. FDA, an office of the U.S. Department of Health and Human Services (DHHS), and the federal agency responsible for protecting the human health from impure and unsafe foods, drugs, cosmetics, and medical devices. Within the FDA, the Center for Biologics Evaluation and Research (CBER) administers the regulation of biologic products under the applicable provisions of the U.S. Food, Drug, and Cosmetics Act. CBER's authority extends to inspecting manufacturer's facilities for compliance with standards; testing products and establishing product standards; and approving the licensing of manufacturers to produce biologic products. FDA regulations governing biologic products are found in 21 CFR.

The FDA regularly inspects MBPI for compliance with regulations pertaining to the manufacture, storage, and testing of safe and effective biologic products. Inspectional Observations are recorded on Form FDA 483. The MBPI was inspected by the FDA in November 1996 at which time deficiencies were noted in some MBPI procedures and record keeping practices. In a letter to the MBPI dated March 11, 1997, the FDA stated that failure to correct these deviations could result in revocation of FDA licensure. The MBPI may remain open and operational while it addresses the deficiencies cited by the FDA.

The Inspectional Observations made by the FDA in the November 1996 inspection were largely administrative in nature. They were principally associated with the lack of written procedures and the failure to follow established written procedures for the manufacturing process for blood derivatives products and rabies vaccine. Deviations cited by the FDA are grouped into the following areas:

- (a) Quality Control. The quality control unit failed to approve or reject all components, procedures, or specifications of the manufacturing process through approval and release procedures.
- (b) Process Procedures. The FDA noted a failure to establish and/or follow written procedures for production and process controls.
- (c) Control Procedures. There was a failure to establish and follow control procedures to validate performance of manufacturing processes that possibly caused variability of in-process material and the product.
- (d) Test Procedures. There was a failure to establish and/or follow test procedures for stability programs for the immune globulin and rabies vaccine, to establish separate or defined areas that would reduce potential contamination or mix-ups, or to maintain or sanitize equipment at appropriate intervals that would reduce malfunction or contamination.
- (e) Calibration. Calibration of equipment was not routinely performed according to written procedures.
- (f) Management. FDA was concerned that management had not exercised control in all matters relating to compliance with federal regulations or to assure that personnel were adequately trained and supervised.
- (g) Housekeeping and Maintenance. Some areas were in a poor state of repair.

The FDA also conducted inspections of the MBPI in May 1993, May/June 1994, and April/May 1995 where deviations from cGMP were noted. Some of these were repeat deviations and a Warning Letter was issued in August 1995. Following the August 1995 Warning Letter, the DoD provided MBPI with assessment and assistance. Corrective actions and the prioritization of these corrective actions were recommended for compliance of the total facility. Following each inspection and the Warning Letter, MBPI corrected some of the deviations, and proposed corrective action for others. In the March 11, 1997 letter, the FDA was concerned that corrective actions promised in the past were not yet completed and that the follow-up inspection showed that long-term corrective action had not been taken. FDA stated that it had no assurance that corrective actions proposed in the January 1997 MBPI response would be properly implemented. FDA served notice in its March 11, 1997 letter of specific requirements to demonstrate or achieve compliance with federal regulations. FDA required a letter from MBPI within 10 days to commit to correct the deficiencies. Further, the FDA required within 30 days of its letter, a comprehensive report and a detailed plan to bring the facility into compliance and to provide proposed timelines for the correction of each deficiency. The MBPI has submitted the letter, the comprehensive report, and the plan to the FDA.

The FDA continues to release lots of MBPI products based on MBPI lot release test results, and any other tests that FDA chooses to perform on MBPI products. In the case of the anthrax vaccine, these tests demonstrate that the final product for distribution meets requirements for product sterility, purity, safety and potency as defined in 21 CFR. Nothing within the FDA inspection of MBPI operations indicates there would be any likely significant adverse impacts resulting from the cited deficiencies. The FDA has indicated that it is not aware of injuries to recipients of MBPI products because of the noted deficiencies (CBER, 1997).

MBPI notified DoD of the results of FDA inspections and the March 11, 1997 letter stating FDA's requirement for concrete commitment to corrective actions. DoD assistance was expanded in response to the March 11, 1997 FDA letter. The increased involvement and

assistance of DoD are expected to improve MBPI's future compliance with FDA administrative requirements.

MBPI prepared a response to the March 11, 1997 letter in which it committed to correcting deficiencies and provided a detailed approach for bringing the facility into compliance with FDA regulations. Among the important approaches in achieving compliance is the transfer of MBPI from state ownership and control to a private sector company. As a state-controlled facility, the MBPI director had little or no control over state maintenance procedures or priorities, or over personnel employed under the civil service system. As a private company, MBPI will be structured in a manner similar to commercial pharmaceutical organizations (see Figure 2-1). The detailed plan submitted to the FDA describes resolution of compliance issues as well as the team engaged in transitioning MBPI to the private sector. Commercial partners involved in bringing MBPI into regulatory compliance include two companies involved in plasma fractionation and childhood vaccines, as well as the DoD with an interest in anthrax vaccine. The detailed plan submitted by MBPI to the FDA also describes the progress in facilities upgrades, management changes, and training in response to Form FDA 483 Inspectional Observations, and commits to timelines for completing changes and corrective measures.

2.7.2 Security Inspections

An evaluation of MBPI security measures was performed by a DoD survey team in 1994. The assessment determined that previous recommendations from a 1990 survey had been successfully implemented.

2.7.3 DA Inspections

Adherence to CDC/NIH Guidelines is required by the DA for work involving biological defense etiologic agents. Such work is monitored and inspected in accordance with 32 CFR 626. At a minimum, pre-award on-site inspections are performed for work involving BL-3 containment and pre-operational inspections of work in which major changes in procedures, facilities, or equipment are made after the pre-award survey. Subsequently, inspections of BL-3 facilities, equipment, and operations are performed annually. 32 CFR 626 specifies that these inspections be conducted by safety and occupational health professionals trained in biological defense research, development, and acquisition operational safety requirements. Inspections of BL-1 and BL-2 facilities engaged in work related to biological defense are conducted prior to contract award and annually thereafter by safety and occupational health professionals or contracting agency representatives trained in biological safety inspection techniques. DA Pam 385-69 (32 CFR 627, *Biological Defense Safety Program: Technical Safety Requirements*, 1995) provides a checklist for performing these inspections.

A representative of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), acting on behalf of the U.S. Army Medical Research and Materiel Command (USAMRMC), conducts an annual inspection of the BL-3 containment facilities at MBPI to ensure compliance with prescribed standards. Records of inspections must be retained by the Health and Safety Officer for at least 3 years. These reviews are conducted using the Basic Checklists for BL-1, BL-2, and BL-3 facilities located in 32 CFR 627. The 1996 USAMRIID review found that the vaccine production facility in Building 12 was in full compliance with

CDC/NIH Guidelines for BL-2 facilities. The review also indicated that the animal test facility in Building 45 (vaccine potency testing) meets or exceeds physical standards for BL-3 facilities and ABL-3 facilities as described in CDC/NIH Guidelines. Operational procedures in Building 45 were also in accordance with those recommended for BL-3 operations by CDC/NIH Guidelines. The USAMRIID inspector recommended the installation of emergency lighting for the animal facility and an alternative to the respiratory protection device currently in use (Hawley, 1996).

2.7.4 Incinerator Inspections

An incinerator inspection on August 14, 1996 by the Michigan Department of Natural Resources, Air Quality Division, resulted in the finding of non-compliance after the inspector observed unacceptable smoke emissions over a 10-minute period (Department of Natural Resource, 1996). MBPI is in the process of identifying all non-animal wastes that may have been disposed by incineration and is arranging for their proper disposal (Nummy, 1997b).

An inspection of the incinerator conducted on April 29, 1997 resulted in the finding of “undetermined status” because the incinerator was not operating at the time of the inspection. The inspection report indicates that the incinerator “appeared capable of operation in compliance” with the permit. The Department of Environmental Quality, Air Quality Division, plans to conduct a follow-up inspection during a period of incinerator operation to document incinerator compliance (Department of Environmental Quality, 1997; McClellan, 1997).

2.7.5 Phase I Environmental Site Assessments

In March 1995, a Phase I environmental site assessment was conducted for the MDPH and a private customer for a construction project at Building 16. The assessment was performed to identify Recognized Environmental Conditions that might pose environmental liabilities at the site. This report found no Recognized Environmental Conditions and soil sampling revealed no contaminants at levels requiring action (Johnson, Johnson & Roy Inc., 1995).

Another Phase I environmental site assessment was conducted in October 1996 as part of a facilities master plan analyzing state buildings at the site. Observations relevant to Building 16 included the presence of a 2,500 gallon underground tank for storing diesel fuel. This double-walled tank was installed in 1993 and is equipped with automatic monitoring sensors. No Recognized Environmental Conditions were observed with regard to this underground storage tank (Smith, Hinchman, & Grylls Assoc., Inc., 1996).

The October 1996 environmental site assessment reported 11 locations within the North Logan/Martin Luther King, Jr., Boulevard complex of government facilities as areas of potential Recognized Environmental Conditions. Neither Building 12 or 16 nor sites adjacent to Building 12 or 16 were among the 11 areas noted (Smith, Hinchman & Grylls Assoc., Inc., 1996).

A survey of both storm and sanitary sewers was conducted in October 1996 within the North Logan/Martin Luther King, Jr., Boulevard complex of government facilities. The survey found that runoff from the site is discharged directly to either Jones Lake or the Reynolds Drain. The report suggested that stormwater management practices should be changed to comply with

standard practices and avert deterioration of receiving water bodies (Smith, Hinchman & Grylls Assoc., Inc., 1996).

2.8 OCCUPATIONAL HEALTH

2.8.1 Medical Monitoring of Personnel

In accordance with CDC/NIH Guidelines, the MBPI requires that workers entering the anthrax vaccine production or potency testing facilities while production or testing is in progress must be immunized by vaccination against anthrax. Immunization requires an initial series of six doses administered over 18 months and a single booster dose annually thereafter.

2.8.2 Medical Monitoring of Vaccine Recipients

Decisions to administer vaccines to military personnel for the purpose of medical biological defense are made by the U.S. Secretary of Defense on advice from the Assistant Secretary of Defense for Health Affairs, and implemented through the Secretaries of the military departments and the Joint Chiefs. Vaccines are provided to military personnel through DoD medical delivery systems and like any biologic product, must be administered under the supervision of a licensed physician. In addition to medical monitoring by primary care practitioners, vaccine recipients are monitored by several mechanisms. Adverse events resulting from the administration of licensed vaccines must be reported through the Vaccine Adverse Event Reporting System (VAERS), a civilian surveillance system established in 1990 and managed by the FDA and the CDC. The primary purpose of the VAERS is to identify rare and previously unrecognized reactions to vaccines (especially newly marketed vaccines) and to monitor the safety of particular lots of vaccines. The data included in this reporting system are the description of the adverse event, date of vaccination, date of onset of the adverse event, and vaccines administered.

Reports to the VAERS may be submitted by anyone, although most reports are received from vaccine manufacturers, health care providers, and state health coordinators. Historically, most reports received are for vaccine reactions seen in young children. FDA physicians are responsible for reviewing selected serious cases. Serious events are also followed by FDA for recovery status.

MedWatch, established in 1993, is another system managed by the FDA for reporting serious adverse events resulting from vaccines. This system differs from the VAERS in that most of its reports are from health care practitioners and it gathers information not only on vaccines but also drugs and medical devices. Data included in this system include age, sex, and weight of the patient; adverse event; date and description of the adverse event; other relevant patient history and test results; a description of the suspect medication or device; and reporter information.

In addition to these systems for monitoring reactions to FDA-regulated products, the DoD and DA have surveillance activities underway or in development for surveying adverse health events and their potential causes. Current military surveillance systems include the Army Medical Surveillance Activity, the Defense Medical Epidemiology Database, and the Uniformed Services Prescription Database Project (Petersdorf et al., 1996). The purpose of

these activities is to enhance understanding about the health and well-being of service personnel by gathering and integrating medical information within select populations (e.g., vaccine recipients) to specific treatments (e.g., vaccines) and/or exposures to hazardous substances or infectious agents.

The product insert included with distributed vials of anthrax vaccine indicates that adverse reactions which may occur with administration of anthrax vaccine adsorbed include mild local reactions (reactions at the site of injection) such as redness and slight tenderness (MDPH, 1987b). These reactions occur in approximately 30 percent of vaccine recipients within 24 hours of injection and subside by 48 hours. Local reactions tend to increase in severity by the fifth injection and then decrease in severity with subsequent doses. Moderate reactions characterized as inflammation reactions greater than 5 centimeters at the site of injection occur in approximately 4 percent of anthrax vaccine recipients. More severe local reactions characterized by swelling of the forearm in addition to a local reaction are less frequent. All local reactions which have been reported in response to anthrax vaccine have been temporary. Systemic reactions, such as generalized weakness and discomfort have been reported in less than 0.2 percent of anthrax vaccine recipients. Fever and chills have been reported “in only a few cases” (MDPH, 1987b). The MBPI recommends that immunization should be discontinued in individuals experiencing systemic reactions (MDPH, 1987b). Like local reactions, the systemic reactions reported have been only temporary.

2.9 SECURITY

The MBPI Plant Protection Unit provides general security for MBPI, monitors all automated systems (security, fire, and energy management), monitors temperature throughout the complex, controls access to MBPI grounds, and responds to emergency situations. The Plant Protection Unit is composed of a chief and ten officers who provide 24 hour-per-day protection. The Michigan State Police advise MBPI security forces and respond to all emergencies (Mattson, 1997).

An 8-foot fence surrounds the MBPI complex. Access to the facilities and grounds is limited by security turnstiles that require card-key use. Access to restricted laboratory buildings is also limited and monitored through card keys. User-specific card keys must be used to enter or exit each laboratory building as well as the MBPI grounds. Security guards can track the location of an individual within the MBPI complex through the card-key system. BL-3 laboratory entry also requires the use of a card-key. Access to the BL-3 facility is further limited to personnel with special authorization. All access into and out of the BL-3 facility is electronically monitored (Mattson, 1997).

Sliding gates operated by security guards provide vehicle access to the MBPI campus. Visitors entering the grounds must register at the security desk, are provided with visitor badges, and are monitored by MBPI personnel upon gaining access. Video surveillance cameras are located at key areas throughout the complex to monitor access to buildings and grounds. Video cameras located at two gate access points leading into the laboratory complex are monitored by guards who maintain communication with these points by intercom (Mattson, 1997).

Two local power companies provide electric power to the facility. Heat and electricity for the complex are provided by the power house which is staffed 24 hours-per-day. Emergency

generators are available in the event that power from both providers is interrupted. Access to buildings is limited in the event of a power outage (Mattson, 1997).

2.10 WASTE STREAM MANAGEMENT

The MDPH Handling and Disposal Manual incorporates the requirements of applicable federal and state regulations and describes the policies and procedures of MBPI with regard to waste stream management (MDPH, 1992d). MBPI personnel are required to follow the waste-handling and disposal procedures outlined in the Manual and any additional procedures which may be applicable to a specific operation.

2.10.1 Wastewater

Wastewater discharged to the sanitary sewer system from MBPI anthrax vaccine production and testing activities must not contain infectious or hazardous materials. All potentially infectious materials must be decontaminated by chemical (chlorine bleach) or physical (autoclave) means prior to discharge to the waste stream (see Section 2.5.2). Liquid wastes containing hazardous chemicals must be disposed of through special waste handling procedures. There are no wastewater collection or containment systems in Buildings 12 or 45. There are capped floor drains in the animal room in Building 45. Only standard disinfectant solutions and bleach enter the drains when uncapped and in use.

The MBPI contributes approximately 12 million gallons of wastewater to the Lansing Municipal Wastewater Treatment Plant per year. The MBPI anthrax vaccine production and testing efforts currently contribute approximately 800,000 gallons per year to this total (6.7 percent). It is anticipated that the proposed increased production volumes will result in an additional 1.2 million gallons of wastewater annually (see Section 5.3.4) (Nummy, 1997c; 1997e).

2.10.2 General Solid Waste

General solid waste generated at MBPI is taken from the compactor on the east side of the Heating Plant (Building 32) to the Wood Street landfill by a commercial refuse service. The MBPI generates approximately 1.4 million pounds of solid waste per year (Nummy, 1997c). Anthrax vaccine production and testing activities currently contribute approximately 3,000 pounds annually to this total (0.2 percent). It is anticipated that the proposed increase in anthrax vaccine production will result in the generation of an additional 3,000 pounds of solid waste yearly (0.6 percent of the MBPI total) (Nummy, 1997c; 1997e).

MBPI activities generate approximately 92,000 pounds of animal bedding annually. The volume of animal bedding generated in housing guinea pigs prior to use in anthrax vaccine potency testing is approximately 3,500 pounds per year. The proposed increase in anthrax vaccine production is not expected to significantly increase the volume of animal bedding generated (Nummy, 1997c).

2.10.3 Regulated Medical Waste

The handling and disposal of medical wastes at the MBPI are regulated by the Michigan Medical Waste Regulatory Act of 1990 (Act No. 368 of the Public Acts of 1978, Part 138, Medical Waste). Medical waste regulated by this Act includes cultures of infectious agents and associated biologicals including laboratory wastes, biological production wastes, discarded live and attenuated vaccine, culture dishes, and related devices; liquid animal wastes; and sharps (materials which pose a puncture risk to human skin). The MDPH Waste Handling and Disposal Manual describes the policies and procedures of the MBPI regarding disposal of medical wastes and incorporates the requirements of the Act. All medical wastes must be placed in closed, intact, leakproof containers labeled with the biohazard symbol. Medical wastes which have been decontaminated must be labeled as such.

MBPI wastes classified as infectious wastes according to Michigan law include the remains of animals used in vaccine potency testing and laboratory wastes such as culture dishes. These wastes must be disposed of by incineration at MBPI. Guinea pig carcasses must be double-bagged and identified with a biohazard label. This bag must then be placed in the MBPI pathological waste incinerator. Anthrax vaccine testing activities produce about 3,000 pounds of infectious wastes per year. It is anticipated that infectious wastes generated yearly at MBPI from anthrax vaccine production activities will be approximately 5,400 pounds following implementation of the proposed action (Nummy, 1997c; 1997e). No animal bedding is used in the conduct of potency testing (Nummy, 1997b).

Potentially infectious wastes are rendered sterile at their site of generation by physical means (autoclave). Autoclave indicator tape must be applied to each container prior to autoclaving. Following sterilization, the indicator tape will read "autoclaved," "decontaminated," or "sterilized" (MDPH, 1992d). Once sterilized, solid wastes must be incinerated in the MBPI pathological waste incinerator and sterilized liquid wastes discharged to the sanitary sewer. Waste HEPA filters that are generated from anthrax vaccine production activities must be decontaminated by paraformaldehyde vapors and autoclaved prior to disposal.

Outdated and unusable containers that have held biologic products or materials must be sterilized by autoclave prior to disposal. The labels must be removed from these containers following sterilization, and the containers must be placed in the designated 55 gallon drums located at the northeast corner of Building 2. Non-burnable waste is removed from the grounds by Granger Container Service, a local contractor, and transported to its landfill location (Charamella, 1997).

Waste needles (used or unused), syringes, Pasteur pipettes, and other materials which pose a risk of skin puncture are included in a category of medical waste called sharps. The MBPI generates approximately 1,000 pounds of sharps per year. Of this total, anthrax vaccine production and testing activities contribute less than 10 pounds (approximately 1.0 percent) (Burgoyne, 1997). The MBPI estimates that the generation of waste sharps will not exceed 10 pounds when production volume increases (Nummy, 1997c). Used disposable needles must be disposed of in puncture-proof containers labeled with the biohazard symbol. Contaminated syringes must be sterilized by autoclave prior to incineration in the MBPI pathological waste incinerator (MDPH, 1992d). All sharps containers must be sterilized by autoclave prior to being taken to the power plant loading area to await pick up by the contracted waste hauler. Sharps containers are required to be sealed, labeled, and placed in leakproof containers during transport (MDPH, 1992e).

2.10.4 Incinerator

Decontaminated solid infectious wastes and animal carcasses (see Section 2.10.3) are incinerated on-site in the MDPH pathological waste incinerator located outside of Building 32. The incinerator is a Consumat Waste Disposal System (Model C-32, Class VI). The incinerator is permitted by the State of Michigan (Permit #76-71I) to burn Type IV waste. The incinerator burns approximately 37,000 pounds of waste per year (approximately 150 pounds per day) (Nummy, 1997b).

The permit to operate the incinerator allows the burning of animal remains and solid organic wastes (MDPH, 1984). The burning of small quantities of plastics, such as the plastic bags in which wastes are contained, is also acceptable (McClellan, 1997). Privatization of MBPI will not change the existing permit to operate the incinerator. When the privatization of MBPI is complete, the new owners are required to submit written notification to the Michigan Department of Environmental Quality, Air Quality Division, regarding the change of ownership (McClellan, 1997; MDPH, 1984). A discussion of incinerator inspection results is located in Section 2.7.4.

2.11 EMERGENCY PROCEDURES

The MDPH Emergency Evacuation Plan contains detailed information for responding to emergency situations (e.g., fire, weather emergencies, medical emergencies, bomb threats). The Michigan State Police currently provides support and protection in the event of an emergency. Following privatization, Lansing police will provide first response in the event of an emergency and fire support will be provided by the City of Lansing Fire Department in accordance with the City of Lansing Ordinance #968, Chapter 234 (Emergency Management). AR385-69 requires that a formal Memorandum of Understanding (MOU) exists between MBPI and the local providers of emergency services (see Appendix B).

2.11.1 Hazardous Chemicals

MBPI procedures for handling hazardous chemical spills are described in the MDPH *General Procedures for Handling Spills* and the MDPH CHP. Spill deactivation procedures, protective clothing, and disposal requirements for specific hazardous chemicals are detailed in these procedures. Laboratories must be equipped with the necessary supplies and inactivating reagents to contain, neutralize, and clean up chemical spills (MDPH, 1992f).

2.11.2 Etiologic Agents

2.11.2.1 Accidents Involving Avirulent *B. anthracis*

The types of accidents which might occur when working with avirulent *B. anthracis* are spilling the spore suspension, spilling the 10 liter seed bottle, and spilling the 100 liter production culture. Written protocols require that avirulent anthrax spills be flooded with bleach using 1 liter of bleach for every 5 liters of spill. To ensure complete decontamination of the spill, a 30-minute contact time between the bleach and the spill is required. Small decontaminated spills may be cleaned with paper towels. Large treated spills may be collected by mops or mopped

down the floor drains. If a large spill is collected in a bucket or mopped down a floor drain, the area of the spill must then be mopped with bleach and discarded down the floor drain. Paper towels, mops, and buckets used to clean up spills must be autoclaved for 60 minutes and then discarded (MDPH, 1990).

2.11.2.2 Accidents Involving Virulent *B. anthracis*

All work with and storage of virulent *B. anthracis* must take place in the BL-3 animal test facility. Potential accidents that may occur when handling virulent anthrax include spilling or dropping the serum bottle or pipette, puncture with a contaminated needle, or the inadvertent production of aerosols. In the event of a spill, personnel wearing the appropriate protective clothing (i.e., long sleeve gown, mask, gloves) would carry out clean-up procedures. Clean-up procedures would include covering the spill area with absorbent materials (e.g., diapers or paper towels) and drenching it with bleach. A 30-minute contact period for the bleach is required to ensure complete decontamination. The absorbent materials used in clean-up procedures are placed in clear plastic biohazard bags and autoclaved for 60 minutes. All materials used for clean-up and all contaminated materials including personal protective equipment must be autoclaved or decontaminated with bleach (MDPH, 1990).

In the event that a person is accidentally punctured with a contaminated needle, the individual must leave the containment area, disrobe, shower, and report in person to the Coordinating Physician (MDPH, 1990). Aerosols resulting from the accidental release of anthrax spore suspension into the air must be treated in the same manner as spills. If spore suspension is detected on surfaces, they must be treated with bleach and collected on paper towels. Used paper towels must be autoclaved for 60 minutes (USAMRDC, 1993a). All accidents and incidents involving either avirulent or virulent *B. anthracis* must be reported to the Coordinating Physician for appropriate evaluation and actions to protect employee health (MDPH, 1990).

2.11.2.3 Accidents and Incidents

There have been no cases of anthrax resulting from occupational exposure to *B. anthracis* since anthrax vaccine production began at this site. Since the MDPH EA was prepared in 1993, there have been no personnel accidents in which medical treatment was required, nor have there been incidents requiring more than routine clean-up or disinfection.

2.11.2.4 Accident Investigation

Laboratory supervisors are responsible for investigating all accidents and incidents and for making recommendations for accident prevention strategies. The MDPH Health and Safety Officer is required by the MDPH CHP to report any incidents of hazardous chemical exposure or situations involving risks to the environment to the laboratory supervisor. Form 141, *Employer's Report of Injury*, and supporting documentation are required to document accidents involving employee injury (MDPH, 1992g).

2.12 SPECIAL CONSIDERATIONS

Anthrax vaccine testing and production activities at MBPI do not involve aerosol testing; work with recombinant DNA; toxins or the generation of waste toxin; radioisotopes; or human subjects.

2.13 ANIMAL CARE AND USE

MBPI must comply with national standards and regulatory requirements regarding the use of animals in its anthrax vaccine production and testing activities. These include the Animal Welfare Act of 1966 (7 USC 2131-2156, as amended) which sets forth standards for humane animal care, handling, treatment, and transportation, and requires licensing of animal dealers. Animal handling and quality of care must be maintained as recommended in the *Guide for the Care and Use of Laboratory Animals* (National Research Council (NRC), 1996). The use of harmful or dangerous viruses, serums, toxins, and other agents in animals in facilities producing or testing biological products at MBPI is regulated by 21 USC 154. MBPI is registered as an animal research facility under both the Animal Welfare Act (USDA license No. 34-R-0027) and the Michigan Public Health Code (No. 31-5) (Nummy, 1997b). The animal safety practices and procedures utilized in MBPI anthrax vaccine potency testing meet or exceed the recommendations for ABL-3 facilities in CDC/NIH Guidelines (CDC/NIH, 1993) as indicated in the 1996 USAMRIID inspection report (Hawley, 1996).

An inspection of animal care and use was performed by the Chief, Animal Use Review Division, USAMRMC, on October 8 and 9, 1996. The inspection found that the MBPI possessed the “expertise and facilities necessary to conduct research using animals” in accordance with the Animal Welfare Act, the *Guide for the Care and Use of Laboratory Animals*, “and pertinent military regulations.” Deficiencies noted in this inspection report were primarily related to the facility and the need for renovations was noted (Ruble, 1996). The inspector noted that MBPI had made program and facility improvements since the previous inspection conducted in August 1994. The inspector also indicated that a USDA inspection of July 11, 1996 revealed no significant deficiencies (Ruble, 1996).

3.0 ALTERNATIVES

3.1 INTRODUCTION

The proposed action is the increased anthrax vaccine production capability at the MBPI through the renovation and expansion of existing anthrax vaccine production facilities and the conduct of increased anthrax vaccine production and testing activities. During the preparation of the EA, two alternatives to the proposed action were identified and are discussed below.

3.2 ALTERNATIVES

3.2.1 Alternative I - Renovation and Expansion of MBPI Facilities and Increased Anthrax Vaccine Production (Preferred Alternative)

Alternative I entails the renovation and expansion of anthrax vaccine production and testing facilities to provide increased production capability at MBPI. Anthrax has been determined by the DoD to be a potential biological warfare agent and the increased production of anthrax vaccine is necessary to meet the needs of the military with respect to immunizing service men and women. This alternative is the preferred alternative because MBPI is the only FDA-licensed anthrax vaccine production facility in existence and therefore the option which best meets the needs of the national defense.

3.2.2 Alternative II - Meeting Increased Anthrax Vaccine Production Needs through a Source Other Than MBPI

This alternative entails conducting anthrax vaccine production and testing activities at a location other than MBPI. This alternative is not the preferred alternative because MBPI is the only existing FDA-licensed anthrax vaccine production establishment. Therefore, a facility other than MBPI would be required to obtain FDA approval prior to commencement of anthrax vaccine production. The FDA approval process for another facility (more than 5 years) would delay vaccine production and consequently delay meeting the need for increased anthrax vaccine production and the needs of the national defense.

3.2.3 Alternative III - Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope (No Action Alternative)

Alternative III involves the continuation of current anthrax vaccine production and testing activities at MBPI in their present scope and in existing facilities. This alternative is not the preferred option because existing facilities are inadequate to accommodate increased production of anthrax vaccine. Alternative III would impair national defense posture by impeding the production of anthrax vaccine for which a need has been determined.

4.0 AFFECTED ENVIRONMENT

4.1 INTRODUCTION

This section of the EA describes aspects of the biophysical and socioeconomic environment (i.e., resource areas) that could potentially be impacted by the proposed action. A more detailed description of the environmental attributes of the site is provided in a previous NEPA analysis (USAMRDC, 1993a).

4.2 LOCATION

MBPI is located in south-central Michigan in Ingham County (Figure 4-1). The MBPI is located in Lansing, the state capital, on North Martin Luther King, Jr. Boulevard (Figure 4-2). Ingham County covers approximately 558 square miles and is part of an urban area known as the Clinton-Eaton-Ingham Tri-county region.

4.3 PLANT AND ANIMAL ECOLOGY

As a result of the urbanization of Lansing, much of the natural wooded areas have been removed. The vegetation of the area consists of crop lands, brush areas, and both deciduous and conifer woodlands. The predominant hardwood trees of Lansing include oak, hickory, and maple. Beech, ash, walnut, and cherry trees are found to a lesser extent in the region. Pine and tamarack conifer stands are also located in Lansing. Grasses, legumes, and other wild herbaceous plants are found in the woodland areas of Ingham County (DOT, 1977; USAMRDC, 1993a).

Because MBPI is located in a well established urban area, it provides only minimal habitat for wildlife. Therefore, the types of wildlife most common to urban residential areas (e.g., squirrels, birds) are found in the vicinity of MBPI. White-tailed deer, fox squirrel, cottontail rabbit, raccoon, opossum, and weasel are wildlife species that are common to northern Lansing and Ingham County (USAMRDC, 1993a).

Marshland areas adjacent to the Grand River and the Red Cedar River provide habitat suitable for a variety of wildlife including waterfowl, reptiles, and small mammals. Migratory waterfowl including various species of teals, mallards, ducks, and geese seasonally inhabit these wetlands. Other wildlife species including muskrat, mink, and beaver thrive in the wetland habitats of Lansing and Ingham County. The shallow, open waters of the wetland areas may also contain numerous species of annual and perennial herbaceous plants (e.g., grasses, rushes) (USAMRDC, 1993a; U.S. Fish and Wildlife Service (USFWS), 1993).

Jones Lake is polluted with nutrients from the drainage of its highly urbanized watershed. Thus it provides only minimal habitat for recreationally important fish species or other aquatic communities (USAMRDC, 1993a). Although the Grand River receives large amounts of both point and non-point pollutants, it supports gamefish populations such as chinook salmon, bass, walleye, and northern pike. Other warm-water fish common in the vicinity of the MBPI include river chub, bluntnose minnow, rock bass, and green sunfish (Hanshue, 1997a).

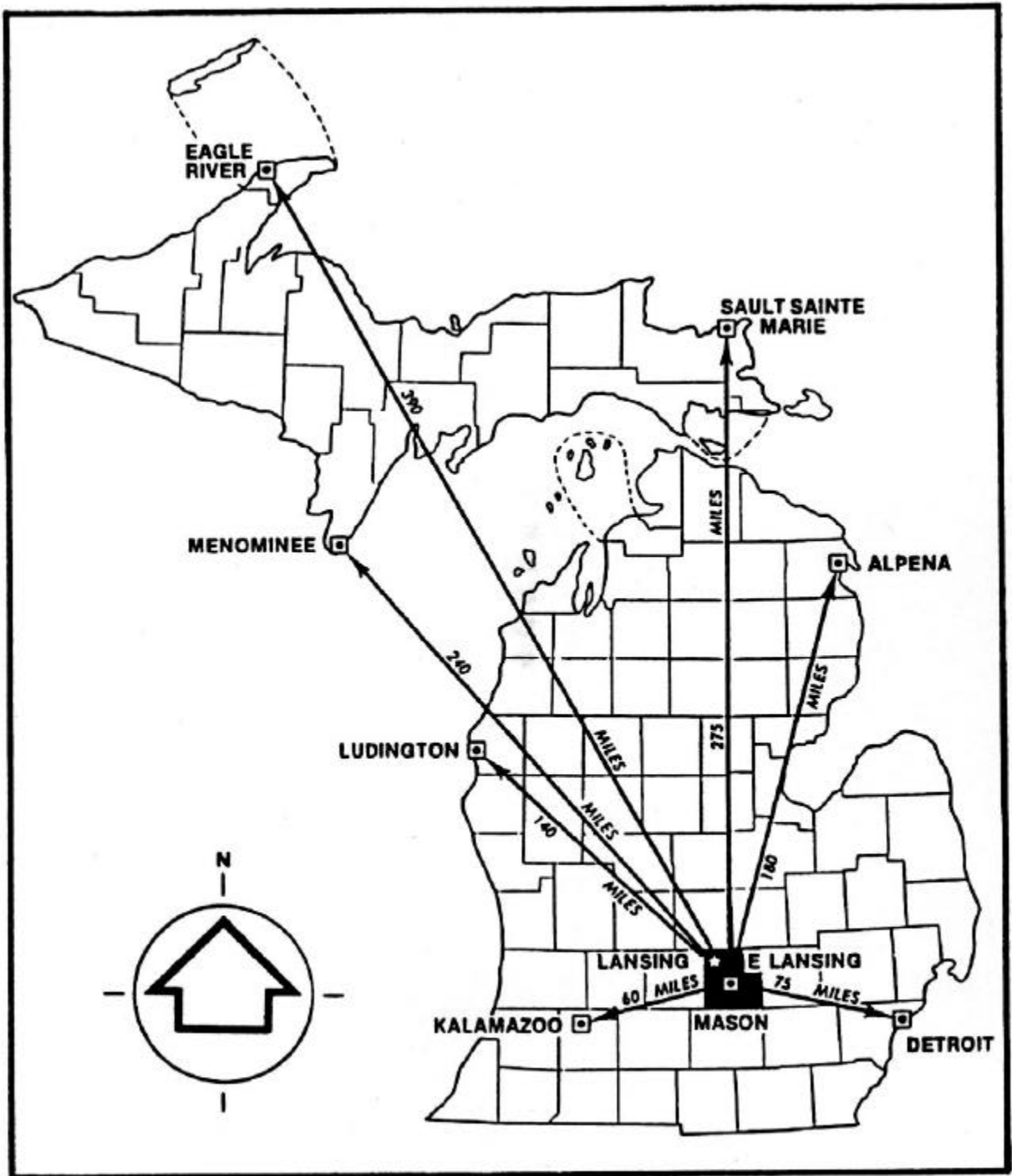


Figure 4-1. Location of Ingham County, Michigan

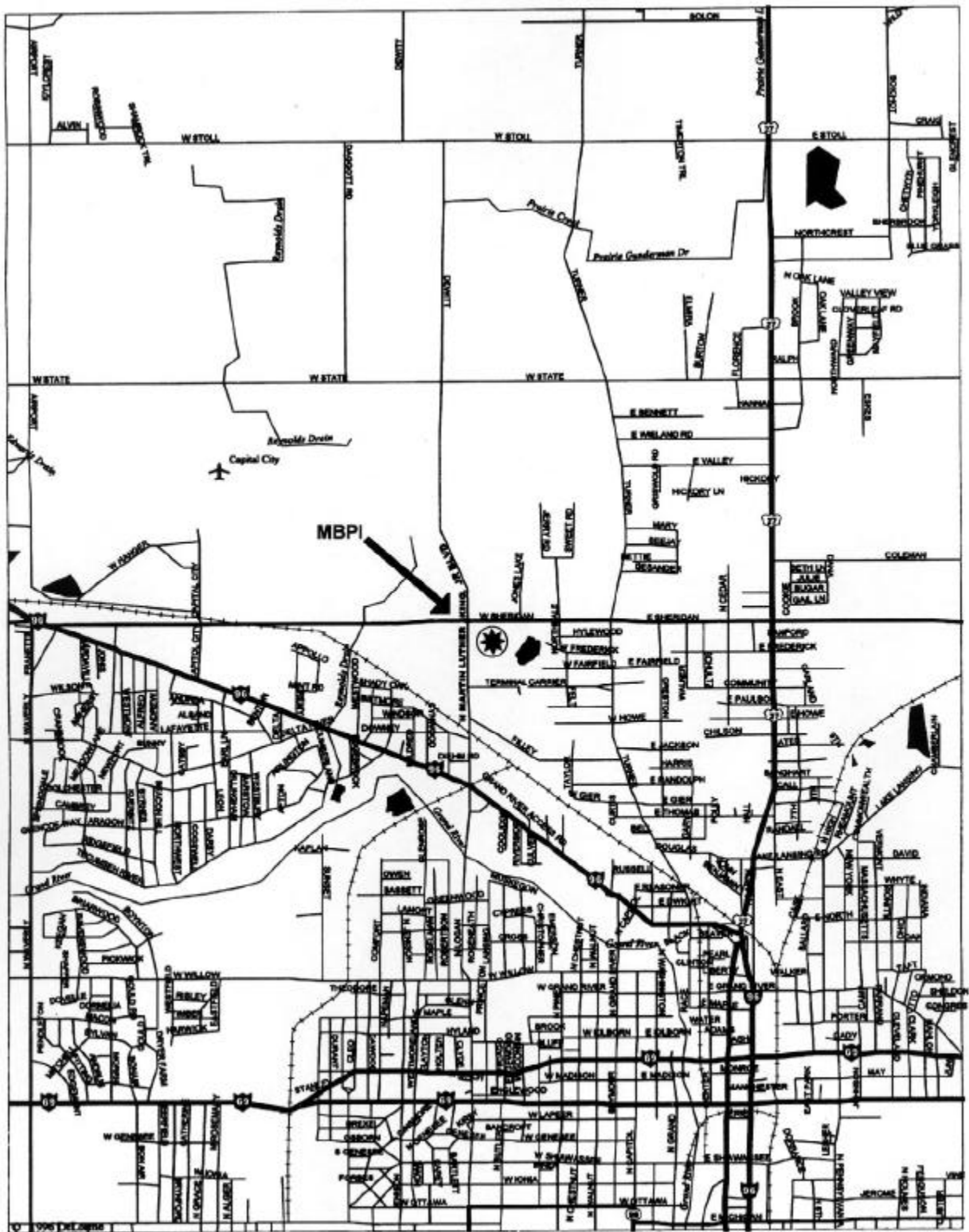


Figure 4-2. Location of MBPI (indicated by ⚙) within Lansing, Michigan

Several threatened and endangered species inhabit portions of Ingham County (see Appendix C). The majority of these species are dependent on large wetlands and undisturbed habitat. Federal or state listed endangered, threatened or otherwise significant species are not known to inhabit the MBPI area or those areas adjacent to the facility (Sargent, 1997). Given the altered environmental characteristics of the area surrounding the MBPI, there is little high quality habitat for most species of wildlife.

4.4 LAND USE

The City of Lansing regulates land use by maintaining a Comprehensive Plan, establishing zoning ordinances, and regulating development on land within its jurisdiction. The North-East portion of Lansing is recognized as one of the four planning areas in the Comprehensive Plan (Lansing Planning Division, 1984; Rieske, 1997). This area of Lansing is characterized by low density residential development and various industrial and business activities. The region surrounding the MBPI consists of light industry and residential areas. Businesses in the area include warehouses, auto repair, offices, and other commercial uses. Land just beyond these industrial areas is zoned for single and multi-family residences (Lansing Planning Division, 1984; Rieske, 1997). The site occupied by MBPI was farmland and woods prior to the 1920s. The first building was constructed on the present day campus in 1926 with most buildings erected between 1945 and 1947 (Smith, Hinchman & Grylls Assoc., Inc., 1996). The State of Michigan has owned the property for more than 70 years. MBPI land use conforms to the current and future development plans within Lansing and Ingham County.

4.5 ENVIRONMENTAL JUSTICE

The percentage of the population living below the poverty level in Lansing is 19.4 percent which approaches the definition of a “poverty area.” Therefore, Lansing can be considered a low income community under Executive Order 12898 (U.S. Census Bureau, 1990). Based upon the data reported in the 1990 Census, the percentage of the minority population living in the area adjacent to the site is 26 percent.

4.6 WATER RESOURCES

4.6.1 Surface Water

The MBPI lies within the Grand River Watershed Basin. The Grand River and the Red Cedar River are two major streams in Ingham County which drain the entire region (Soil Conservation Service, 1977). The Grand River originates south of Jackson, Michigan and flows northward along western Ingham County with an average flow of 900-1100 cubic feet per second (cfs). The Grand River joins the Red Cedar River, located in the northern part of the county, and flows westward. The Grand River and the Red Cedar River converge at Lansing and flow out of the county at its northwest corner and eventually empty into Lake Michigan. The Grand River is located approximately 0.75 miles southwest of the MBPI (Hanshue, 1997b). Historically, this river has received large volumes of both point and non-point pollutants from its highly urbanized watershed (USAMRDC, 1993a). The water quality of the Grand River is good in that portion nearest to the MBPI (Hanshue, 1997b). The MBPI does not lie within the

100-year floodplains of the Red Cedar River or the Grand River (National Flood Insurance Program, 1981).

Jones Lake is the major surface waterbody near the MBPI. This is a relatively shallow lake (15 to 20 feet maximum depth) that forms the eastern boundary of the MBPI. Jones Lake is classified as a permanent palustrine (standing water) open water ecological system by USFWS. Areas surrounding Jones Lake on the southeast and southwest sides are classified by USFWS as seasonal palustrine emergent wetlands (USFWS, 1993). The water quality of Jones Lake is not monitored by the State of Michigan because it is a private lake (Hanshew, 1997b).

Soils in the North-East area of Lansing can be characterized into two categories: 1) well and moderately drained soils, and 2) poorly drained soils (Lansing Planning Division, 1984). Local drainage around the MBPI is good. The majority of surface drainage from the MBPI flows toward the southwest and the Grand River. Due to the topography of the area, only a limited amount of surface drainage enters Jones Lake. Combined sanitary and storm sewers receive stormwater runoff from MBPI. The combined sewer system transports runoff and sewage to the Lansing Municipal Wastewater Treatment Plant (WWTP) (USAMRDC, 1993a).

The Lansing Municipal WWTP is located on the Grand River and serves the northeastern portion of Lansing. This plant operates under National Pollutant Discharge Elimination System (NPDES) permit No. MI0023400, which allows the discharge of wastewater into the Grand River. The Lansing Municipal WWTP is in compliance with NPDES limits (Kaiser, 1997). This plant is a conventional activated sludge WWTP and provides tertiary treatment to wastewater. A peak flow of 95 million gallons per day (mgd) was recorded in February 1997. The plant discharges an average of approximately 22 mgd (8 billion gallons per year) to the Grand River (Kaiser, 1997).

4.6.2 Groundwater

The Lansing area uses groundwater from the Saginaw Formation as a source of water. The Lansing Board of Water and Light supplies MBPI with its water. Groundwater is pumped from a number of wells in the Lansing area (100 to 550 feet below the ground surface) and is then treated at a conditioning plant located on Cedar Street before being distributed to MBPI. The quality of the groundwater is generally good and meets all standards before being distributed (Smith, 1997; USAMRDC, 1993a).

4.7 GEOLOGY

The geologic environment includes earth resources such as soil characteristics, topography, fossils, minerals, and bedrock composition. Federal regulations governing geological impacts relate to protection of groundwater, surface water, and wetlands.

Ingham County is situated in the Southern Michigan/Northern Indiana Till Plains Province. This area is characterized by recessional moraines and till plains. Elevations range from about 600 feet to more than 1,000 feet above mean sea level (msl). Soils in the area were primarily derived from glacial movements approximately 15,000 years ago and contain large amounts of loamy sand and clay (USAMRDC, 1993a). The North-East area of Lansing is predominantly flat with little variation in elevation. Elevations in the Lansing area range from a low of 810 feet

to 895 feet (Lansing Planning Division, 1984). The elevation of the MBPI campus ranges from 840 and 850 feet (USAMRDC, 1993a).

The predominant soil type at the MBPI is Urban Land Marlette Complex, which makes up more than 6 percent of the soils in Ingham County (USAMRDC, 1993a). Typically this soil has a fine sandy loam surface layer and is found in 2 to 12 percent slopes. The permeability of Marlette soil is moderate or moderately slow, the available water capacity is high, and surface runoff is moderate. The water table may be as high as 2.5 to 6 feet during the winter and spring. Potential habitat for wetland plants and associated wildlife is poor. These soils are well suited for agricultural purposes and support grasses, herbaceous plants, hardwood trees, coniferous plants, and associated wildlife. These soils are considered moderately suitable for light industrial development (Soil Conservation Service, 1977).

4.8 HISTORIC AND CULTURAL RESOURCES

Historic and cultural resources include historic sites, architecturally important buildings, locations which have cultural significance to the local community, and unique geological locations.

4.8.1 Historic

Confirmed historic architectural resources are not located adjacent to or on the MBPI property. However, the Michigan Bureau of History is currently conducting a Section 106 review (part of the National Historic Preservation Act of 1966) of the MBPI property. The state's preliminary evaluation indicates that because of the age of the MBPI complex, it may be eligible for listing in the National Register for Historic Places (Eckert, 1992).

4.8.2 Archaeological

A search of existing resources revealed no known archaeological sites within the grounds of the MBPI. No sites of archaeological importance have been uncovered at the MBPI in the course of past construction and maintenance activities. The degree of disturbance at the MBPI indicates that there is little possibility for the site to contain significant archaeological deposits.

4.9 AGRICULTURE

Agricultural resources include crops and livestock in the areas surrounding MBPI. Section 1539 of the Farmland Protection Policy Act of 1981 (PL 97-98) regulates the protection of agricultural lands by minimizing unnecessary and irreversible conversion of farmland to nonagricultural uses by federal programs and assuring compatibility with state, local, and private programs governing farmland. The Act pertains to prime, unique, and statewide or locally important farmland.

4.10 CLIMATE

The climate of Lansing fluctuates between continental and semi-marine. Continental climate is characterized by little wind and pronounced fluctuation in temperature (i.e., hot weather in

summer and severe cold in winter). The semi-marine climate of the area is due to the influence of the Great Lakes and is controlled by the force and direction of the wind. The lake effect from the Great Lakes produces cooler summers and milder winters in the Lansing area. Mean seasonal temperatures range from 24°F during the winter to 69°F in the summer. The minimum and maximum temperature extremes recorded for Lansing are -29°F and 100°F, respectively. Precipitation in Lansing is fairly evenly distributed throughout the year. The average annual precipitation for the region is approximately 31 inches per year. Lansing receives a moderate amount of snowfall annually with 52 inches per year. The prevailing wind direction is from the southwest and wind speeds average 9.9 miles per hour (National Oceanic and Atmospheric Administration (NOAA), 1995).

4.11 ENERGY RESOURCES

Depletable resources consumed by the MBPI include natural gas and fuel oil. Natural gas is provided by the Consumers Power Company (Lansing Regional Chamber of Commerce, 1995).

4.12 NOISE

Negative impacts of noise on animals and humans include annoyance, permanent or temporary hearing loss, speech interference, sleep interference, health impacts, and harm to agricultural livestock and wildlife. The Noise Control Act of 1972 as amended (PL 92-574, USC 4901-4918) governs noise control for protection of public health. Generally, noise is regulated at the state and local level.

Noise generated from off-site external sources contribute more to the general noise level at the MBPI than noise generated by MBPI activities. Sources of external noise include the Lansing Airport and traffic from North Martin Luther King, Jr. Boulevard.

4.13 ODORS

Waste generated through research activities at the MBPI include contaminated laboratory materials, animal carcasses, wastewater, and medical waste. These wastes must be rendered sterile through heat treatment and/or incineration prior to disposal. Transiently offensive odors may result from heat treatment and incineration; however, they are typically localized in area and time and are rapidly dispersed in the ambient atmosphere. There are no records of complaints of offensive odors originating from the MBPI.

4.14 SOCIOECONOMIC ENVIRONMENT

Lansing had a reported population of 127,812 in April, 1996 (Christian, 1997). Proportions of the population by race in 1990 were approximately 75 percent Caucasian, 18 percent African American, and 7 percent "other." The median age for residents of the county is 29.9 years. Eighteen percent of the residents of Ingham County 25 years of age or older have completed at least 4 years of college (U.S. Department of Commerce, 1991).

The major industries of Lansing are retail sales and manufacture of durable goods (U.S. Department of Commerce, 1991). According to the Michigan Employment Security Agency,

61,475 people were employed in the City of Lansing in 1996 (Mechem, 1997). The unemployment rate for Lansing has decreased from approximately 6 percent in 1992 to approximately 4.7 percent in 1996 (Lansing Regional Chamber of Commerce, 1995; Mechem, 1997). The MBPI employs approximately 157 full-time employees and 2 part-time employees (Nummy, 1997d). The median family income in Lansing in 1989 was \$31,587. The per capita income was just over \$12,000 (U.S. Department of Commerce, 1991). In 1990, there were 53,919 housing units in Lansing (U.S. Department of Commerce, 1991). The average price for a residential home in 1994 was \$67,355 (Lansing Regional Chamber of Commerce, 1995).

4.15 TRANSPORTATION

The MBPI can be reached via a number of roadways in the region including U.S. Route 127, U.S. Route 27, Interstate 69, and Interstate 96. Michigan Routes 36, 43, 52, and 99 also serve Ingham County. The MBPI is locally accessible from North Martin Luther King Jr. Boulevard on the south, Dewitt Road on the north, and Sheridan Road on the east. Traffic congestion is not a problem in this area of Lansing (Lansing Planning Division, 1984; Rieske, 1997). Public transit to the MBPI within the Tri-county region is available by the Capital Area Transit Authority (CATA) system (Lansing Regional Chamber of Commerce, 1995).

Commercial airline service to the MBPI within the Lansing region is available at Capital City Airport which is located approximately one mile west of the MBPI. Additional commercial service is available at Detroit Metropolitan Airport and Grand Rapids International Airport.

4.16 AIR QUALITY

Ingham County is in attainment for all criteria air pollutants. The Michigan DEQ Air Quality Division maintains two ozone monitors in Lansing (Rusch, 1997). All air pollutants have remained below the standards set by the State of Michigan since 1982 (Rusch, 1997).

4.17 PUBLIC OPINION

There are no records of citizen complaints from members of the public regarding the MBPI (Johnson, 1997).

4.18 HUMAN POPULATIONS

The renovation and expansion of vaccine production facilities and increased anthrax vaccine production capacity at MBPI may affect human populations. There are at least four groups of people with the potential for impact from the proposed action. These groups include workers performing renovation and expansion tasks, MBPI anthrax vaccine production and testing workers, anthrax vaccine recipients, and individuals living near MBPI facilities.

5.0 ENVIRONMENTAL AND SOCIOECONOMIC CONSEQUENCES

5.1 INTRODUCTION

In this section, the potential environmental consequences of the renovation and expansion of existing anthrax vaccine production facilities, and their operation as described in Section 2.0 will be discussed. This section will identify and analyze potential cause and effect relationships which may exist between the proposed action and potential impacts, if any. Such an analysis entails detailing the potential impacts associated with the proposed action at MBPI that may not necessarily occur, but which are reasonably foreseeable. This analysis will inform the decision makers and the public in making reasonable choices among the alternatives.

The term “consequence” refers to the results of an event or events without consideration of probability. Where possible and appropriate, potential events will be characterized both in terms of their potential consequence and the probability that they will occur. Consequences of the proposed action on the public, on workers, and on vaccine recipients will be considered. Direct, indirect, and cumulative effects also will be considered.

5.2 ASSESSMENT APPROACH

This EA incorporates analyses from previous NEPA analyses which assessed similar or identical actions to determine potential impacts of the proposed action described in Section 2.0. This approach entails referencing specific relevant analyses, discussions, and conclusions of those documents without providing detailed discussions in this EA.

There are three types of previous NEPA analyses which are relevant to the proposed action. The first group of documents includes site-specific EAs for facilities involved in research and development for the DA that use biologic defense etiologic agents (USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; Walter Reed Army Institute of Research (WRAIR), 1993; USAMRDC, 1993b; U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), 1992).

The second class of NEPA analyses is the BDRP FPEIS (DA, 1989) which programmatically assessed the environmental consequences associated with the activities involving the use of biologic defense etiologic agents. The analyses performed in the BDRP FPEIS included examination of general laboratory activities; laboratory work involving the use and handling of biological defense etiologic agents (microorganisms and toxins); decontamination of materials, equipment, and/or laboratories; and the disposal of biological materials. These analyses also considered the transport of biohazardous organisms into and out of facilities; waste stream management; facility operation and maintenance; animal care and use; and the testing of products or product prototypes in human volunteers.

The final group of relevant NEPA analyses includes The Salk Institute - Government Services Division (TSI-GSD) EA (USAMMDA, 1992) and the MDPH EA (USAMRDC, 1993a). Both of these facilities produce vaccines for the DA. The MDPH EA (USAMRDC, 1993a) is particularly relevant because that document analyzed the environmental impacts associated with anthrax vaccine production activities at the same facility which is the subject of the proposed action. In

the present EA, the environmental impacts identified and quantified in the 1993 EA will be used to evaluate the incremental environmental impacts directly attributable to the proposed action. The TSI-GSD EA analyzed the environmental impacts of the production of biological defense vaccines (e.g., vaccinia, WEE, EEE, VEE, Q-fever, tularemia, and improved anthrax vaccines). TSI-GSD, a biological products scale-up manufacturing facility under contract to the U.S. Government, develops, produces, and tests investigational vaccines for clinical trials. In addition, both MBPI and TSI-GSD receive, store, inventory, and ship vaccines as directed.

In the following sections (Section 5.3.1 through Section 5.3.20), the historical experience at this particular site is used to predict potential environmental consequences by resource area from the proposed action and the alternatives. Under each resource area potential environmental impacts are identified. Potential environmental impacts from the renovation and expansion phase of the proposed action and the operation of the facility phase of the proposed action are separately evaluated under each resource area. In Section 5.4, the potential environmental impacts of implementing the proposed action and the alternatives are summarized and compared.

5.3 POTENTIAL ENVIRONMENTAL CONSEQUENCES OF THE PROPOSED ACTION

5.3.1 Plant and Animal Ecology

Local plant and animal ecology could be negatively impacted during renovation through the destruction of habitat from fugitive dust, erosion, and noise. Best Management Practices (BMPs) relevant to fugitive dust, erosion control, and noise will fully mitigate negative impacts to the local plant and animal ecology. During renovation and construction activities at this site in 1993 no identifiable impacts occurred to the local plant and animal ecology because BMPs were applied during the renovation and construction phase (USAMRDC, 1993a).

Potential impacts to plant and animal resources could occur during the operation phase of the proposed action from inadequate waste stream management or the use of endangered species in research and production activities. In no instance have activities which will be conducted at the MBPI been demonstrated to impact the plant and animal ecology of the site (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). This is consistent with the previous experience at this site (USAMRDC, 1993a). Wildlife and/or endangered species will not be used in the conduct of MBPI activities. It is unlikely that production of anthrax vaccine at MBPI will impact the plant and animal ecology of the site because potential impacts have been and will continue to be mitigated by adherence to regulations regarding protection of wildlife and disposal of waste. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) will also have negligible effects on plant and animal ecology because of adherence to regulations regarding waste treatment.

5.3.2 Land Use

Land use impacts related to renovation could potentially occur from excessive erosion from the site during this phase of the proposed action. As discussed above, application of BMPs during renovation will prevent excessive erosion from the site.

MBPI activities might potentially impact land use patterns if those activities are not in character with the designated land use. Existing land use patterns in the vicinity of MBPI include commercial and retail establishments, parking lots, residential areas, and light industry. In all previous cases, the conduct of similar or identical activities that will be performed at the MBPI have been in accordance with existing land use patterns (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). It is not anticipated that land use will be negatively impacted in the area adjacent to the MBPI campus because the proposed action conforms to pre-existing land use patterns. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) will also likely have negligible impacts on land use patterns.

5.3.3 Environmental Justice

Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority and Low Income Population*, requires federal agencies to address significant adverse impacts of their actions on minority or low income populations. The U.S. Census defines the poverty level as the income level, based on family size, age of householder, and the number of children under 18 years of age, that is considered too low to meet essential living requirements without regard to the local cost of living. A “poverty area” is defined by the Census Bureau as an area in which at least 20 percent of the population lives below the poverty level.

For the purpose of Executive Order 12898, race refers to census respondents’ self-identification of racial background and includes persons who identify themselves in the broad categories of Caucasian, African American, Asian, and “other race.” Census data also include those individuals who identify themselves as of Hispanic origin which refers to ethnicity and may include Spanish-speaking persons of any race.

According to the 1990 census, the percentage of the population living below the poverty level in Lansing is 19.4 percent. According to the definition of a “poverty area,” Lansing approaches this definition and therefore can be considered a low income community under Executive Order 12898. The percentage of the minority population living in Lansing is 26 percent.

During the renovation and expansion phase of the proposed action, minority and/or low income communities could be economically impacted if they are excluded from the economic benefits arising from renovation activities. All vendor and contractors participating in the renovation phase of the proposed action will be required to adhere to Equal Opportunity Employment (EOE) and Affirmative Action considerations as identified in 29 CFR 1608.1

Anthrax vaccine production activities that have been performed at MBPI in the past have not resulted in significant adverse impacts to minority or low income populations. As detailed below, activities associated with the proposed action are not expected to result in significant adverse impacts to air quality, noise levels, visual resources, transportation systems, odors, utilities, energy supplies, waste generation, or historic and cultural resources. Implementation of the proposed action, or Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax

Vaccine Production Activities in Present Size and Scope) are not anticipated to have any disproportionately high adverse human health or other environmental impacts on low income or minority populations.

5.3.4 Surface Water

The handling and disposal of wastewater originating from research laboratories are regulated by DoD, Army, federal, state, and local policies, guidelines, and regulations. Section 402 of the Clean Water Act (CWA) (40 CFR Part 230) mandates the NPDES (40 CFR Part 122) and is implemented by the DA through AR 200-1. The EPA and/or state regulatory agencies regulate wastewater discharge. All point source discharges to navigable waters are required to possess an NPDES permit. The NPDES permit process includes application, issuance, and compliance monitoring. Wetlands are protected by Section 401 and Section 404 of the CWA which regulate unnecessary destruction of wetland communities from discharge of dredged or fill material (40 CFR Part 6).

Wastewater discharge compliance is highly site-specific because the quality and quantity of pollutants which can be discharged are determined by the characteristics of the receiving water body and its use as designated by the state. Effluent limitations include restrictions on quantities, rates, and concentrations of chemical, physical, or biological components of the waste stream. The states are usually delegated authority to administer and monitor discharge permits within their jurisdictions. State regulations governing the qualitative and quantitative characteristics of the discharge may be more stringent than those of the EPA.

Potential impacts to surface water could result from the renovation phase of the proposed action if excessive erosion from the MBPI site entered Jones Lake or the Grand River. Appropriate use of BMPs during the renovation and expansion phase will mitigate this potential impact. Moreover, the MBPI site is 0.75 miles from the Grand River, further reducing the potential for adverse impacts to surface water.

Production of anthrax vaccine could potentially impact surface water resources if the wastewater from these activities is discharged into a waterbody without adequate treatment. Such untreated discharge would consume dissolved oxygen from the water possibly resulting in the death of aquatic life.

No significant impacts to surface water resources have resulted from research, development, test, and evaluation (RDT&E) activities and production of biological defense vaccines in the more than 50 years of the conduct of these activities (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). Treated wastewater has been discharged from this site for more than 50 years with no significant impacts to the Grand River. Wetlands would not be impacted since wastewater will not be discharged to wetlands. The increase in wastewater from 100,000 gallons to 600,000 gallons anticipated to result from implementing the proposed action represents 0.0075 percent of the average annual wastewater to the Lansing Municipal WWTP. The Lansing Municipal WWTP is in compliance with the conditions of its NPDES permit. Potential impacts to surface water will be mitigated by adherence to appropriate regulations for treatment of wastewater and adherence to regulations governing handling, use, and disposal of etiologic agents. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs

through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) would either relocate the negligible impacts to another geographical location (Alternative II) or would continue the negligible impacts at MBPI (Alternative III).

5.3.5 Groundwater

Groundwater protection is mandated by the Resource Conservation and Recovery Act (RCRA) (40 CFR Parts 261-270), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (40 CFR Parts 300-399), and the Safe Drinking Water Act (SDWA) (40 CFR Part 144). Regulations protecting groundwater resources are concerned primarily with possible contamination of groundwater by leachates from landfills, underground storage tanks, deep well injection of wastes, and hazardous wastes sites. The SDWA requires state agencies to identify and protect critical aquifer areas.

Groundwater resources could be impacted during renovation if the aquifer were penetrated when laying the foundation. However, because the groundwater at MBPI is at least 100 feet below the surface, it is unlikely that groundwater resources will be impacted.

Groundwater resources could be impacted by anthrax vaccine production operation if wastewater pipes from MBPI to the Lansing Municipal WWTP leaked into the groundwater. A recent inspection of the sanitary sewer pipes at MBPI revealed some impeded sewer lines, but there were no indications that groundwater contamination had resulted from leaking wastewater pipes at MBPI. Moreover, the depth of the groundwater in the region (100 feet to 550 feet) reduces the likelihood of this potential impact. The sewer pipes were flushed in the fall of 1996 (vanRavenswaay, 1997).

Previous NEPA analyses for similar and identical activities to those that will be conducted at MBPI indicate no adverse significant impacts have resulted to groundwater resources (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992; U.S. Army Garrison (USAG), 1997). Impacts to groundwater resources resulting from implementation of the proposed action at MBPI or any of the alternatives would be unlikely because compliance with the regulations designed to protect groundwater resources will mitigate or eliminate negative impacts to groundwater.

5.3.6 Geology

Geologic resources could be impacted during renovations if excessive erosion occurred from the site. At the present time, precipitation runoff from the campus discharges directly to either Jones Lake or to other drainage pathways leading to the Grand River. The runoff may contain high concentrations of suspended solids and salts because of the development of the campus (Smith, Hinchman & Grylls Assoc., Inc., 1996). It is unlikely that renovation and expansion at MBPI will negatively impact geologic resources because adherence to BMPs during renovation will mitigate significant impacts. In previous cases where renovation or new construction has occurred, including this site, erosion impacts have been characterized as negligible (USAMRDC, 1993a; USAMMDA, 1992).

In no instance have activities similar or identical to those that will be conducted at MBPI been shown to negatively impact the geology of the site (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). The laboratory facilities at MBPI are situated in conformance with local topography and have not caused excessive erosion.

The environmental audit of the MBPI campus conducted by Smith, Hinchman & Grylls Assoc., Inc., in 1996 indicated that the site possessed Recognized Environmental Conditions affecting geologic resources at some locations. Recognized Environmental Conditions means “the likely presence of hazardous substances or petroleum products on a property under conditions that indicate an existing release, a past release or a material threat of a release into structures or the property, or into the groundwater or surface water of the property” (Smith, Hinchman & Grylls Assoc., Inc., 1996). The majority of the Recognized Environmental Conditions identified related to leaking drums containing unknown substances and above ground fuel tanks on the MBPI campus. The MBPI has removed or has plans to remove these Recognized Environmental Conditions from the campus.

The contribution to erosion by landfill disposal of waste materials has been consistently characterized as negligible (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). The volume of wastes which MBPI would contribute to the Granger Companies landfill under the proposed action is far less than 0.01 percent of the material entering the landfill (Wright, 1997). Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) would either relocate the negligible impacts to geologic resources to another geographical location (Alternative II) or continue the negligible impacts at MBPI.

5.3.7 Historic and Cultural Resources

The National Historic Preservation Act of 1966, as amended (PL 89-665), mandates a national policy for protection and restoration of significant historic, architectural, archaeological, or cultural resources. The 1980 amendments to the act provide for historic preservation costs to be included in project planning and budgeting. The DA implements the National Historic Preservation Act through NEPA, AR 200-2, and AR 420-40, *Historic Preservation*. The State Historic Preservation Officer (SHPO) is primarily responsible for ensuring adherence to the National Historic Preservation Act.

During renovation at the MBPI, as well as during the conduct of anthrax vaccine production activities, significant historic or cultural resources could be impacted if conducted near significant sites in a manner which altered or lessened these resources, including disturbance of archaeological sites. Negative impacts to historic and archaeological resources resulting from activities which are conducted at MBPI have not been demonstrated (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992).

The potential for the proposed action to impact historic or cultural resources is negligible because significant historic and archaeological sites have not been identified on the MBPI campus. The age of some of the buildings on the MBPI/MDPH campus, however, makes them

potentially eligible for listing on the National Register for Historic Places (USAMRDC, 1993a). Prior to renovation, building plans must be reviewed by the SHPO and their potential impact to significant historic and cultural resources determined. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) would relocate potential impacts to another geographical area (Alternative II) or continue the negligible impacts at this location (Alternative III).

5.3.8 Agriculture

Negative impacts to agricultural resources during renovation or during the conduct of anthrax vaccine production activities could occur if these activities lessened the agricultural characteristics of the adjacent land. Agricultural resources have not been negatively impacted by similar or identical activities which are performed at MBPI (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). Identical activities have been conducted at the MBPI for more than 50 years without appreciable impacts to agricultural resources. Adherence to the Farmland Protection Policy Act will fully mitigate any impacts to agricultural resources. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) would likely relocate negligible impacts to agricultural resources (Alternative II) or continue existing negligible impacts at this location.

5.3.9 Climate

Air quality of a region may influence local climate. Potential impacts to air quality are discussed in Section 5.3.15.

5.3.10 Energy Resources

Energy resources could be adversely impacted if renovation activities or anthrax vaccine production consumed excessive quantities of energy. Energy consumption will result from commuting of the workforce and from movement of renovation equipment and materials. This energy consumption will be transitory and is unlikely to significantly impact the total consumption of the Lansing area. At similar locations where renovation and expansion have been required, including the MBPI in 1993, the amount of energy consumed has been characterized as negligible (USAMMDA, 1992).

Energy consumption associated with the routine production of anthrax vaccine will occur from the commuting activities of the workforce and electrical consumption required to produce anthrax vaccine and properly dispose of waste products. The workforce involved in the production of anthrax vaccine is expected to increase from 10 people to 12 people with the implementation of the proposed action. The amount of energy consumption is expected to increase by approximately one-third, primarily from waste disposal operations.

In previous assessments of similar or identical activities that are conducted at MBPI, the amount of energy consumption related to these activities has been demonstrated to be negligible when compared to the total consumption of the area (DA, 1989; USAMRIID, 1991;

USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). Although the conduct of MBPI activities will likely consume greater quantities of electricity per square foot than non-containment facilities, it is unlikely that these activities will significantly impact total energy consumption in the Lansing region. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) would cause the negligible energy consumption to be shifted to another geographical location (Alternative II) or a negligible savings in energy consumption at the present location (Alternative III).

5.3.11 Noise

Excessive noise levels from renovation activities as well as routine anthrax vaccine production activities could impact the health of the workforce and the public, and alter the local plant and animal ecology. A temporary increase in the noise level at MBPI will occur during the renovation phase; however, adherence to appropriate OSHA standards to protect the workforce will maintain noise levels at acceptable levels (29 CFR 1926.52).

Noise impacts have not been identified as a significant concern in previous evaluations of similar or identical activities which are conducted at MBPI (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). The activities which are conducted at MBPI, are by their very nature, quiet. Noise sources from MBPI activities could include transportation of employees and vendors to the site, and exhaust fans. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) would result in relocation of these negligible noise impacts to another geographical location (Alternative II) or continuance of the existing negligible noise impacts at MBPI (Alternative III).

5.3.12 Odors

Odors may be associated with certain MBPI activities such as incineration or heat treatment of wastes. The CAA and state regulations govern odors associated with incineration and disposal activities.

Unpleasant odors resulting from similar or identical activities which are conducted at MBPI have been identified as an area of minor concern (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). These odors, however, are transitory and rapidly diluted in the atmosphere. There have been no written complaints regarding odors from the MBPI complex (Davis, 1997b). Adherence to applicable regulations governing disposal of wastes, particularly those related to incineration, will mitigate minor impacts from MBPI activities to the local environment. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) would shift these minor odors to another geographical location (Alternative II) or continue the generation of minor odors at the present location (Alternative III).

5.3.13 Socioeconomic Environment

Positive impacts to the local economy will occur from the renovation phase of the proposed action. Local vendors and construction contractors will benefit from the work associated with renovation.

The conduct of anthrax vaccine production activities at MBPI will have an impact on the local economy. The conduct of similar or identical activities which are performed at MBPI have been shown to have a minor positive impact on local economies (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). The economic impact associated with implementing the proposed action would likely be a minor positive impact to the Lansing region. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) would place these minor socioeconomic benefits at another location (Alternative II) or cause a continuation of the minor positive impact at MBPI.

5.3.14 Transportation

An insignificant negative impact to the local transportation network will result from the commuting activities of the workforce and suppliers involved in the renovation phase of the proposed action. These impacts will be temporary and are likely to be insignificant since the MBPI site is located on the outskirts of the Lansing metropolitan region.

The impacts to transportation resources in the Lansing region associated with the routine production of anthrax vaccine are negligible. The proposed action will result in an increase of two employees and will not appreciably impact local transportation patterns. Previous evaluation of the impacts of similar or identical activities which are performed at MBPI on local transportation resources also indicated negligible impacts (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). There is no reason to believe that the production of anthrax vaccine at MBPI will significantly impact transportation resources because these activities will be conducted at an existing site and will not significantly add to existing traffic patterns. Impacts to transportation resources under the other alternatives will also be negligible.

No potential impacts associated with the shipment of etiologic agents will occur at MBPI with implementation of the proposed action. Transportation of etiologic agents, including virulent *B. anthracis*, to or from MBPI will be in compliance with requirements of 32 CFR 626 and 627 and will result in negligible impacts.

5.3.15 Air Quality

Evaluation of the quality of air in the area surrounding a site includes examination of primary and secondary standards and emission standards for hazardous air pollutants (HAPs) as set forth in the Clean Air Act (CAA) of 1990. Primary standards are designed to protect health, whereas secondary standards are intended to prevent environmental and property damage. According to the CAA, HAPs are chemicals that cause serious health and environmental hazards.

The CAA of 1990 added new provisions for air toxics and tightened air quality standards. Under the CAA, the EPA adopted the National Ambient Air Quality Standards (NAAQS) to control a select group of widely occurring pollutants. The NAAQS pollutants are carbon monoxide (CO), nitrogen oxides (NO_x), sulfur dioxide (SO₂), volatile organic compounds (VOCs), lead (Pb), and particulate matter. The provisions of the CAA are only applicable to major (large) sources of air pollution.

Under the CAA, a geographic area in which levels of a criterion air pollutant meet the health-based primary standard (NAAQS) for the pollutant is called an attainment area. A non-attainment area is a geographic area in which the level of a criterion air pollutant is higher than the level allowed by the NAAQS. One single location may be in attainment for one pollutant and simultaneously have unacceptably high levels of another criteria air pollutant. Therefore, an area can be both in attainment and non-attainment at the same time.

The Air Quality Division of the Michigan DEQ regulates the air quality of Ingham County. The State of Michigan incorporates national air quality standards (i.e., the NAAQS) into the standards set by the state pursuant to the CAA.

Incinerators are classified as major sources of air pollution under the CAA. The incinerator located and operated at MBPI is subject to the provisions of the CAA. The use of incinerators is regulated by federal, state, and local laws which set standards and limits for emission volumes and composition, and in some states, the quality (including biological quality) of incinerator ash. Environmental control of biological air quality by HEPA filtration during routine operations of containment facilities is described in CDC/NIH Guidelines (1993).

The air quality of Lansing could be impacted by fugitive dust emissions from the site and commuting activities of the workforce and suppliers during the renovation phase of the proposed action. Adherence to BMPs regarding fugitive dust emissions will mitigate these temporary impacts. The commuting activities of the workforce and suppliers will likely be an insignificant portion of the total transportation activity in the Lansing area. The impacts on local air quality from renovation will be negligible.

During the anthrax vaccine production phase of the proposed action, potential adverse impacts to air quality and local climate could result from commuting of the workforce, waste disposal activities, and air exhaust from biomedical laboratories. As discussed above, the commuting activities of the workforce are unlikely to cause significant impacts to the air quality of the Lansing region. The MBPI incinerator could impact air quality if it emits more pollutants than allowed under its permit. The MBPI incinerator received a notice of violation in late 1996 by the State of Michigan for opacity emissions (smoke emissions) (Michigan Department of Natural Resources (DNR), 1996). An inspection conducted in April 1997 found that the incinerator “appeared capable of operating in compliance” with the conditions of its permit, but the inspector was unable to verify this because the incinerator was not operating at the time of the inspection (Michigan Department of Environmental Quality, 1997). The MBPI is assessing their incinerator usage and waste disposal operations to ensure compliance with existing standards (Nummy, 1997b). The Michigan DEQ, Air Quality Division, plans follow-up inspection to document the compliance of incinerator operations (Michigan Department of Environmental Quality, 1997; McClellan, 1997). Environmental control of biological air quality

by HEPA filtration during routine operations of containment facilities is described in CDC/NIH Guidelines (1993).

Previous NEPA analyses indicate that adverse impacts to air quality resulting from biological defense RDT&E and vaccine production activities have been negligible (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). The high efficiency of HEPA filtration in preventing the escape of etiologic agents from biomedical laboratories has been previously discussed in the CDC/NIH Guidelines (1993) and the BDRP FPEIS (DA, 1989). Ingham County is in attainment for all criteria air pollutants. The proposed action is not expected to significantly increase the amount of wastes incinerated at MBPI. Therefore, the impacts of MBPI activities on local air quality are likely to be minor. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope) would result in either relocation of the minor impacts (Alternative II) or a continuation of the negligible impacts presently existing at MBPI (Alternative III).

5.3.16 Public Opinion

Public opinion toward a proposed action must be considered to the maximum extent practicable in accordance with NEPA and AR 200-2. Evaluation of public opinion includes an assessment of national and/or local perception of issues.

Potential criticisms of the proposed action may include the perceived potential for this activity to be used for offensive purposes, the efficacy of biological defense vaccines, distrust of the military, and whether the military should be involved in vaccine production. Public opinion has been an issue in the conduct of biological warfare defense research and development activities and was extensively discussed in the BDRP FPEIS. Some public concerns relate to the existence of biological defense programs *per se*; others to the intent, need for, and benefits of such programs. Other concerns are specific to the impacts of actions, such as the use of animals in vaccine production, the use of vaccine products in military and civilian personnel, medical surveillance, and potential drug interactions. Issues such as these are not unique to the production of anthrax vaccine at MBPI but are concerns associated with vaccine production and testing activities in general.

The government and facilities supported by the government (e.g., MBPI, TSI-GSD) do not engage in work related to the production or use of offensive biological weapons as required by the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction* (Biological Weapons Convention of 1972) to which the U.S. is a signatory.

5.3.17 Program Benefits

The anthrax vaccine produced at MBPI is determined to be essential to the national defense. In addition to anthrax vaccine production, there are several programs throughout the DoD directed toward developing medical (e.g., prevention, treatment) and non-medical (e.g., detection systems, protective gear) defenses against biological warfare agents. The DoD has determined that biological defense vaccines (e.g., anthrax vaccine) are needed for protecting

service men and women against morbidity and mortality resulting from the hostile use of biological warfare agents. In addition, vaccines are used to protect personnel engaged in biological warfare defense research activities which put them at potential risk of exposure to these agents. DoDD 6205.3 (*DoD Immunization Program for Biological Warfare Defense*) emphasizes the importance of FDA licensure for resulting vaccines “to ensure that service members are afforded the same level of safety and protection as the civilian populace for similar medical products.” This has been reinforced by the Assistant Secretary of Defense for Health Affairs, the military departments, and the Joint Chiefs of Staff.

5.3.18 Human Health and Safety

5.3.18.1 Public Health and Safety

Neither the proposed renovation nor the routine production of anthrax vaccine at MBPI pose a significant threat to public health and safety because of the use of carefully considered and applied safety/containment procedures and practices. In addition, the release of infectious agents from vaccine development and production activities to the environment is prevented by adherence to regulations directing the decontamination of all potentially infectious liquid, air, and solid wastes prior to discharge.

The issue of public health related to vaccine development and production has been examined in the course of evaluating the operations of biological defense medical research facilities and production facilities on a programmatic level and on a site-specific basis (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). There have been no instances of infection or disease in the surrounding on or off campus communities, including MBPI, resulting from the conduct of these activities, and a very small number of laboratory acquired infections in workers (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). This information is consistent with the experiences of a broad range of laboratories throughout the U.S. (CDC/NIH, 1993; USAMMDA, 1992).

5.3.18.2 Worker Health and Safety

The actual risk to the MBPI workforce of contracting anthrax during the production and testing of anthrax vaccine is low and is further ameliorated by vaccination, redundant safety equipment, extensive safety procedures, and training (see Section 2.0). The lack of evidence of significant negative impacts associated with the conduct of similar work at facilities currently and historically engaged in the conduct of biological defense vaccine research, development, testing, and production of vaccines is indicative that the actual risks to MBPI workers will continue to be low. There have been no cases of laboratory-acquired anthrax since the 1950s (CDC/NIH, 1993; Kaufman, 1992). At the MBPI there have been no cases of anthrax resulting from occupational exposure to *B. anthracis* since anthrax vaccine production began at the site (Davis, 1997b). Since the MDPH EA was finalized in 1993, there have been no personnel accidents in which medical treatment was required nor have there been incidents requiring more than routine clean-up or disinfection (Nummy, 1997d). This record validates that consistent application of, and adherence to, regulations and recommended practices and procedures effectively reduce the potential for adverse impacts to worker health and safety.

Workers involved in the production and testing of anthrax vaccine are vaccinated against anthrax, and minor reactions to vaccination occur sporadically (see Section 5.3.18.3). There have been no adverse reactions among MBPI workers requiring medical attention beyond that which the nurse in the MBPI clinic can provide. There have been no reactions requiring emergency room treatment, hospitalization, or the care of a physician (Nummy, 1997d).

5.3.18.3 Health and Safety of Vaccine Recipients

Vaccine Recipients - It is anticipated that the recipients of the anthrax vaccine acquired by the DoD produced at MBPI will be soldiers for whom the threat of possible exposure to biological warfare agents has been established, and workers with the potential for exposure to biological warfare agents through their roles in laboratories or production facilities. DoD policy directs that personnel assigned to high-threat areas, predesignated for possible crisis response, or those employees identified and scheduled for deployment on an imminent or ongoing contingency operation to a high-threat area should be immunized against biological warfare agents for which appropriate vaccines are available. In addition, the CDC/NIH Guidelines (CDC/NIH, 1993) advise that when appropriate vaccines exist, workers should be vaccinated. 32 CFR 626 defines DA policy and guidance for the vaccination of workers engaged in work with biological defense agents.

Risks Associated with Vaccination - Vaccination with any product is not without risk. Biomedical researchers have and are continuing to improve many widely used vaccines (e.g., pertussis, measles, polio) to reduce the inherent risks associated with their use. As with “conventional” vaccines, there are potential risks associated with the administration of biological defense vaccines. Risks to vaccine recipients vary with each vaccine. Individuals also vary in their responses to vaccines. These risks include those reactions which are manifested with the initial administration of vaccine and those which are manifested at some later time.

DoD’s experience with MBPI-produced anthrax vaccine has been very positive. Recipients of the anthrax vaccine are estimated at 150,000 individuals involved in the Gulf War, 1,000 lab workers and individuals participating in DoD studies, and 400-500 doses/year for those individuals involved in non-DoD work. The safety record for this product is excellent. For example, adverse reaction reports (from 16,500 doses in several clinical trials) show that no reaction or mild reactions were reported in 86 percent to 97 percent of those individuals receiving the initial series, and 77 percent to 97 percent of those individuals receiving booster doses. During the 5-year period, severe local reactions were reported for 1 percent or less of the doses. All local reactions to anthrax vaccine were reversible. Only four systemic reactions (chills, fever and aching) were reported for a 24-hour period, but resulted in no chronic or permanent health consequences. There have been no reports of adverse events related to anthrax vaccine received during or since the Gulf War.

Interactive Effects of Vaccines and Other Agents - The potential for adverse interactions among vaccines and drugs, immunoglobulin products, other vaccine products as well as with other biologics have been studied. In general, individuals with a compromised (less effective) immune system from either genetic or disease processes (e.g., human immunodeficiency virus) are at greater than normal risk of adverse reactions. Selected drug effects (e.g., immunosuppression) may be altered by concurrent vaccine administration. Simultaneous and

sequential exposures to combinations of vaccine products have resulted in reduced vaccine immunogenicity.

In considering the potential for adverse impacts in the target population, it must be remembered that service members must be in good health to serve and to be retained on active duty. Additionally, DoDD 6205.3 directs that vaccines be administered with enough lead time for recipients to develop immunity well before their potential exposure to threat agents. The health of the recipient population and the lead time for observing adverse health effects minimize the potential for adverse impacts. Additionally, should there be adverse impacts, effects would be restricted to the recipient with minimal or no potential for adverse impacts in the larger population.

The Committee to Study the Interactions of Drugs, Biologics and Chemicals in the U.S. Military Forces recently prepared a report entitled *Interactions of Drugs, Biologics, and Chemicals in U.S. Military Forces* (Petersdorf *et al.*, 1996) which presented a preliminary evaluation of the potential for biologics and vaccines to interact with other substances which also may be administered to military personnel. The Committee did not find any basis for “extraordinary concern” regarding potential interactions of militarily relevant drugs, biologics, and chemicals. Moreover, the Committee specifically rated the potential for anthrax vaccine to interact with drugs, other biologics or chemicals as very low.

5.3.18.4 Accidents and Incidents

The activities, procedures, and operations used in handling etiologic agents during the conduct of MBPI activities are consistent with those examined in the BDRP FPEIS (DA, 1989). In that evaluation, the likelihood of escape and survival of infectious agents outside of a facility, such as the site where anthrax activities will occur was considered, using Maximum Credible Event (MCE) methodologies (see Appendix 9, BDRP FPEIS). MCEs are considered worst case events which realistically might occur, although the probability of such events occurring is very low.

Although the BDRP FPEIS evaluated MCEs applicable to RDT&E activities and MBPI activities involve production, the MCEs considered in the BDRP FPEIS apply. The amount of virulent (capable of causing disease) organisms used in the production of anthrax vaccine at MBPI will not differ quantitatively from the amounts evaluated in the BDRP FPEIS. At the point in the vaccine production process when large suspensions of biological materials (e.g., 100 liters) are being produced, avirulent (not capable of causing disease) strains are used.

5.3.19 Consequences of Actions Abroad

Executive Order 12114, *Environmental Effects Abroad of Major Federal Actions*, directs both the DA and the FDA to consider the environmental effects of their actions abroad. Environmental analyses and documentation will not be required for the proposed action since the production of anthrax vaccine will not occur outside of the United States.

5.3.20 Environmental Consequences of FDA-Cited Deviations at the MBPI

It is unlikely that the FDA-cited deficiencies have resulted or will result in significant adverse impact. While the deficiencies identified by the FDA may increase the potential for adverse

environmental consequence, the probability of such an adverse consequence occurring is very low. The FDA did not identify any adverse impacts to the environment, including impacts to human health, resulting from the deviations noted. For additional information about FDA inspections of MBPI see Section 2.7.1.

The potential for the FDA-cited deviations detailed in the March 11, 1997 letter to result in environmental consequence has been analyzed (see Section 2.7.1). In general, the deviations are not relevant to the resource areas described in Section 4.0, and in all cases the potential for environmental impact is minor to negligible. Environmental attributes having the potential for impact from FDA-cited deviations include energy resources (see Sections 4.11 and 5.3.10), public opinion (see Sections 4.17 and 5.3.16) and public health and safety (see Sections 4.18 and 5.3.18.1). In addition, the potential for accidents and incidents may be impacted (see Section 5.3.18.4). Table 5-1 summarizes the potential for environmental impact associated with relevant FDA-cited deviations.

Table 5-1. Environmental Impact Analysis of FDA-Cited Deviations

Environmental Resource Area	FDA-Cited Deficiency and Potential Environmental Impacts
Energy Resources	Cited deviations related to equipment calibration have the potential to result in negligible negative impact. Failure to calibrate recording devices resulted in minor increased energy consumption associated with a freezer operating at lower than required temperature. Cited deviations related to housekeeping have the potential to result in negligible impact. Failure to clean and maintain equipment may result in less than optimal energy use.
Socioeconomic Environment	The correction of FDA-cited deficiencies will result in transient increased employment and sales of goods and services that will have a negligible to minor positive impact on the local economy.
Public Opinion	Potential minor negative impacts associated with publicity of the FDA deviations are mitigated by MBPI's continued authorization to remain operational and release product; FDA's statement that it is unaware of negative impact to product recipients; and the continued acceptance and use of MBPI products (e.g., CDC use of MBPI immune globulin during a hepatitis A outbreak in March/April 1997).

Environmental Resource Area	FDA-Cited Deficiency and Potential Environmental Impacts
Public Health and Safety	Negative impacts to public health and safety have not been identified from the conduct of MBPI operations. Deviation from cited FDA regulations (e.g., improper segregation of work areas, inadequate training, insufficient housekeeping practices) might result in the increased potential for negative impact to public health and safety. Potential negative impacts might include infection or injury. The risks to public health and safety will be negligible.
Worker Health and Safety	Negative impacts to worker health and safety have not been identified from the conduct of MBPI operations. Deviation from cited FDA regulations (e.g., improper segregation of work areas, inadequate training, insufficient housekeeping practices) might result in the increased potential for negative impact to worker health and safety. Potential negative impacts might include infection or injury. The risks to worker health and safety will be minor.
Health and Safety of Vaccine Recipients	Negative impacts to the health and safety of vaccine recipients have not been identified. The potential for adverse impacts to vaccine recipients is negligible. Deviation from FDA regulations might result in the increased potential for negative impacts to vaccine recipients if procedural and verification safeguards for product quality and effectiveness are diminished. The reliance of FDA standards and reliance on test data as a precondition of product release and human use prevent potential adverse impacts. Product testing is a proven effective measure to protect vaccine recipients. The FDA is unaware of injuries to recipients of MBPI products because of the noted deficiencies. The FDA permits the MBPI to continue producing and distributing vaccines and other biologic products for human and veterinary use.
Accidents and Incidents	Negative impacts due to accident or incident have not resulted from MBPI operations. Deviation from FDA regulations may result in an increased potential for accident or incident if management emphasis and requirements for development, training, and application of safe procedures and control mechanisms are inadequate.

5.3.21 Cumulative Impacts

The CEQ regulations implementing NEPA define cumulative impacts to the environment as those effects resulting from the impact of the proposed action when combined with past, present, and future actions (40 CFR 1508.7). Thus, cumulative impacts are the sum of all direct and indirect impacts, both adverse and positive, that result from the incremental impacts of the action when added to other past, present, and reasonably foreseeable future actions regardless of source. Cumulative impacts may be accrued over time and/or impacts in conjunction with other pre-existing effects from other activities in the area (40 CFR 1508.25).

Activities qualitatively and quantitatively similar to the proposed action at MBPI have been performed at this geographical location for more than 50 years without evidence of adverse cumulative impacts to the environment. It is unlikely that cumulative impacts will result from implementation of the proposed action.

5.4 COMPARISON OF THE PROPOSED ACTION AND THE ALTERNATIVES

As detailed in Section 5.3.1 through Section 5.3.20 and summarized in Table 5-2 and Table 5-3, no significant environmental impacts are anticipated with implementation of the proposed action.

The probable environmental impacts resulting from implementation of the alternatives do not differ significantly from the proposed action (see Table 5-4). Implementation of the no action alternative would eliminate the minor adverse impacts associated with implementation of the proposed action.

Table 5-2. Summary of Potential Environmental Impacts Related to Renovation and Expansion Activities at MBPI

Environmental Attribute	Potential Environmental Impacts
Plant & Animal Ecology	There will be negligible adverse impacts to aquatic or terrestrial communities as a result of renovation/expansion at MBPI. Due to the overall urbanization of the Lansing region, the terrestrial community located at MBPI is very limited. Soil erosion and sedimentation control measures during renovation/expansion will fully mitigate impacts to aquatic life in Jones Lake and the Grand River.
Land Use	The environmental impacts on land use associated with renovation/expansion at MBPI will be negligible, approximately 0.20 acres (8,800 ft ²). The addition to Building 16 will conform to existing land use patterns.
Environmental Justice	No adverse impacts to minority or low-income populations are anticipated to result from renovation/expansion at MBPI. No adverse impacts to minority or low-income populations have been identified at this site.
Surface Water	Renovation/expansion will negligibly impact surface water resources in the vicinity of MBPI.
Groundwater	Renovation/expansion will negligibly impact groundwater resources because groundwater at MBPI is approximately 100 - 550 feet below the surface.

Environmental Attribute	Potential Environmental Impacts
Geology	It is likely that renovation/expansion at MBPI will negligibly impact geological resources since BMPs will be used to mitigate impacts.
Soils	A minor negative impact on local topography and erosion will result from renovation/expansion. Soil erosion and sedimentation control measures, or BMPs will be utilized to mitigate impacts.
Historic & Cultural Resources	The potential for renovation/expansion to impact historic or cultural resources is negligible because no significant historic or cultural resources are located on or adjacent to MBPI.
Agriculture	Agricultural resources will be negligibly impacted by renovation/expansion at MBPI. Adherence to the Farmland Protection Policy Act will fully mitigate any impacts to agricultural resources.
Energy Resources	Negligible impacts to energy resources are anticipated from renovation/expansion. It is anticipated that these activities will have a negligible negative impact on depletable resources.
Noise	Noise levels resulting from renovation/expansion at MBPI will be minor and temporary.
Odors	Renovation/expansion will generate some minor odors temporarily affecting the immediate environment of MBPI.
Socioeconomic Environment	A minor positive impact to the economy of Lansing will result from the proposed action.
Transportation	Shipment of materials related to renovation/expansion and the commuting activities of construction workers may cause some minor temporary traffic congestion at MBPI.
Air Quality	Fugitive dust and increased vehicular emissions will be temporarily generated by renovation/expansion. Renovation/expansion impacts on air quality will be temporary and minor.
Human Health & Safety	Dangers always exist during renovation/expansion and will therefore present a minor adverse impact to construction workers. Compliance with OSHA regulations during renovation/expansion will ensure protection of the workforce and the public.
Cumulative Impacts	Significant adverse cumulative impacts are not anticipated from renovation/expansion at MBPI.

Table 5-3. Summary of Potential Environmental Impacts Related to Anthrax Vaccine Production Activities at MBPI

Environmental Attribute	Potential Environmental Impacts
Plant & Animal Ecology	Potential impacts to plant and animal resources could occur from MBPI activities involving waste stream management, but potential impacts will be mitigated by adherence to regulations regarding protection of wildlife and waste disposal.

Environmental Attribute	Potential Environmental Impacts
Land Use	It is not anticipated that land use will be negatively impacted by anthrax vaccine production operations at the MBPI. MBPI activities will conform to existing land use patterns since activities will be conducted in existing facilities.
Environmental Justice	No adverse impacts to minority or low-income populations are anticipated to result from anthrax vaccine production activities. No adverse impacts to minority or low-income populations have been identified at this site.
Surface Water	Anthrax vaccine production activities at the MBPI could potentially impact surface water quality if the wastewater from these activities is discharged without adequate treatment. Potential negative impacts to surface water resources will be mitigated by adherence to regulations for treatment of wastewater and the use of prescribed methods of handling, use, and disposal of etiologic agents which render microorganisms harmless prior to entry into the waste stream. Wetlands would not be impacted since wastewater will not be discharged to a wetland.
Groundwater	The potential for anthrax vaccine production activities at the MBPI to impact groundwater resources is very low; however, leaks from sewage pipes is a potential impact. Compliance with regulations designed to protect groundwater resources will mitigate or eliminate significant impacts to groundwater at MBPI.
Geology	No erosion will result from the conduct of anthrax vaccine production activities at the MBPI and therefore geological resources will not be adversely impacted.
Historic & Cultural Resources	The potential for anthrax vaccine production activities at the MBPI to impact historic or cultural resources is negligible because no significant historic or cultural resources are located on or adjacent to the MBPI.
Agriculture	Agricultural resources are unlikely to be impacted by anthrax vaccine production activities at the MBPI because there is minimal potential for these activities to lessen the agricultural characteristics of the land.
Climate	Anthrax vaccine production activities at the MBPI could impact air quality and climate by increasing pollution through several pathways including energy consumption, commuting workforce, incinerator activities, and air exhaust from biomedical laboratories. This adverse impact is likely to be minor.
Energy Resources	Anthrax vaccine production activities conducted in BL-2 and BL-3 facilities will likely consume greater quantities of electricity per square foot than non-containment facilities but this is unlikely to adversely impact air quality.
Noise	Noise levels resulting from anthrax vaccine production activities at the MBPI will be minor and will not significantly add to the noise level of the MBPI campus.

Environmental Attribute	Potential Environmental Impacts
Odors	Unpleasant odors may result from the sterilization of MBPI waste material generated by anthrax vaccine production. However, these odors are transitory and rapidly diluted in the atmosphere. Adherence to regulations governing the disposal of wastes will mitigate the minor impact to the local environment.
Socioeconomic Environment	Conduct of anthrax vaccine production activities at the MBPI will result in a minor positive impact on the local economy in Lansing.
Transportation	It is not anticipated that anthrax vaccine production activities at the MBPI will significantly impact transportation resources because these activities will be conducted at an existing site and will not significantly add to the existing traffic burden.
Air Quality	The impacts of anthrax vaccine production activities at the MBPI on local air quality are likely to be minor. Potential impacts on air quality resulting from increased pollution from energy consumption, commuting workforce, incineration activities, and air exhaust from biomedical laboratories will be mitigated by adherence to the CAA and CDC/NIH Guidelines.
Public Opinion	The production of biological defense vaccines is controversial because of issues relating to the perceived potential for this research to be used for offensive purposes, distrust of the military, the use of soldiers as research subjects, vaccine efficacy, informed consent of soldiers, and whether the military should be involved in vaccine production.
Program Benefits	Anthrax vaccine protects service men and women against morbidity and mortality resulting from the hostile use of <i>B. anthracis</i> as a biological warfare agent and protects personnel engaged in biological warfare defense research activities which put them at potential risk of exposure to this agent.
Public Health & Safety	Anthrax vaccine production activities at the MBPI are not likely to pose a significant threat to public health and safety because of the use of carefully considered safety/containment procedures and practices. Decontamination of all potentially infectious wastes prior to discharge prevents the release of infectious agents to the environment and is required by law.
Worker Health & Safety	Workers engaged in biological warfare defense research activities risk exposure to etiologic agents. The actual risk to the MBPI workforce of contracting anthrax is small and is further ameliorated by vaccination. No employees of MBPI have contracted anthrax in more than 30 years.
Health & Safety of Vaccine Recipients	Potential risks are associated with the administration of any vaccine. The health and safety record of anthrax vaccine is excellent. The administration of anthrax vaccine to soldiers is managed by DoD medical authorities.

Environmental Attribute	Potential Environmental Impacts
Accidents & Incidents	It is extremely unlikely that etiologic agents will be released to the environment from MBPI. Redundant containment and safety procedures minimize risks to the public and workforce. MCEs including aerosol release, escape of an infected rodent, terrorist act, disgruntled employee, and unexpected external events were examined in the BDRP FPEIS and found to pose only a negligible risk. Because the assumption for these MCEs regarding the quantities of etiologic agents are directly comparable to the MBPI activities with <i>B. anthracis</i> , it is concluded that risks to the public and the workforce from MBPI activities are very small.
Consequences of Actions Abroad	The proposed action does not involve actions abroad.
Interactive Effects of Vaccines & Other Agents	The health of the recipient population and the lead time for observing adverse health effects minimize the potential for adverse impacts. Adverse health impacts associated with anthrax vaccine are very minor.
Cumulative Impacts	Significant adverse cumulative impacts are not anticipated from the implementation of the proposed action. Similar and identical activities have been conducted at this particular site for more than 50 years with no appreciable cumulative impacts to the environment. Continuation of similar and identical activities at MBPI is unlikely to result in significant cumulative impacts to the environment.

Table 5-4. Comparison of the Potential Environmental Impacts of the Proposed Action and the Alternatives

Environmental Attribute	<u>Alternative I</u> Renovation and Expansion of MBPI Facilities and Increased Anthrax Vaccine Production	<u>Alternative II</u> Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI	<u>Alternative III</u> Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope (No Action Alternative)
Plant & Animal Ecology	Negligible	Negligible	Negligible
Land Use	Negligible	Negligible	Negligible
Environmental Justice	Negligible	Negligible	Negligible
Surface Water	Minor Negative	Minor Negative	Minor Negative
Groundwater	Negligible	Negligible	Negligible
Geology	Negligible	Negligible	Negligible
Historic & Cultural Resources	Negligible	Negligible	Negligible
Agriculture	Negligible	Negligible	Negligible
Climate	Negligible	Negligible	Negligible

Environmental Attribute	<u>Alternative I</u> Renovation and Expansion of MBPI Facilities and Increased Anthrax Vaccine Production	<u>Alternative II</u> Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI	<u>Alternative III</u> Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope (No Action Alternative)
Energy Resources	Minor Negative	Minor Negative	Minor Negative
Noise	Negligible	Negligible	Negligible
Odors	Minor Negative	Minor Negative	Minor Negative
Socioeconomic Environment	Minor Positive	Minor Positive	Minor Positive
Transportation	Minor Negative	Negligible	Negligible
Air Quality	Minor Negative	Minor Negative	Minor Negative
Public Opinion	Minor Negative	Minor Negative	Minor Negative
Program Benefits	Significant Positive	Significant Positive	Positive

Environmental Attribute	<u>Alternative I</u> Renovation and Expansion of MBPI Facilities and Increased Anthrax Vaccine Production	<u>Alternative II</u> Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI	<u>Alternative III</u> Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope (No Action Alternative)
Human Health & Safety			
• Public Health & Safety	Negligible	Negligible	Negligible
• Worker Health & Safety	Minor Negative	Minor Negative	Minor Negative
• Accidents & Incidents	Negligible	Negligible	Negligible
Cumulative Impacts	Minor Negative	Minor Negative	Minor Negative

5.4.1 Alternative I - Renovation and Expansion of MBPI Facilities and Increased Anthrax Vaccine Production (Preferred Alternative)

This alternative entails renovation and expansion of existing MBPI facilities to facilitate increased production of anthrax vaccine in accordance with FDA standards. The DoD Mission Needs Statement for Biological Defense articulates the importance of medical biological defense products to military readiness. The increased production of anthrax vaccine at the MBPI will ensure an adequate supply of anthrax vaccine for Joint and Service-unique requirements as the Deputy Secretary of Defense has directed.

The proposed action will be conducted at facilities with an experienced workforce already engaged in the conduct of identical activities. Consistent with the present evaluation, previous analyses of activities at facilities engaged in RDT&E and production of biological defense vaccines concluded that there was minimal potential for adverse impact to either human health or the environment (DA, 1989; USAMRIID, 1991; USAMRDC, 1993a; USAMMDA, 1992; WRAIR, 1993; USAMRDC, 1993b; USAMRICD, 1992). This option is the only alternative which meets the needs of the national defense. Therefore, Alternative 1, renovation and expansion of MBPI facilities and increased production of anthrax vaccine at the MBPI in its planned scope, is considered the preferred alternative.

5.4.2 Alternative II - Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI

This alternative includes suspension of anthrax vaccine production and testing activities at the MBPI, and transferring all or part of this work to another geographical location. Constructing a new facility at another location or renovation of an existing facility have the potential for negative impacts on the environment as a result of the construction efforts.

Transferring MBPI anthrax vaccine production to another location would require the same controls, regulatory compliance, and licensure by the FDA. The net result is envisioned to be the same; i.e., potential minor adverse impacts on health of the workforce and no significant adverse effects on the environment. This alternative is not envisioned to have any beneficial environmental effect over the preferred alternative.

It would take approximately 5 years for another facility to become licensed by the FDA to produce anthrax vaccine, assuming this entity possessed the technical data package developed by the MBPI to produce and test anthrax vaccine. Implementation of this option would result in an interim period before a new facility becomes operational during which the demand for anthrax vaccine could not be met. Because implementing this alternative will not meet the current demands for production of anthrax vaccine, it is not the preferred alternative.

5.4.3 Alternative III - Continue Current MBPI Anthrax Vaccine Production Activities in Present Size and Scope (No Action Alternative)

The no action alternative is not preferred because it will neither address nor meet DoD requirements to protect service men and women from anthrax, a potential biological warfare agent. Sufficient quantity of FDA-licensed anthrax vaccine is not available from stockpiled supplies or for direct purchase in the event it is needed for protection of service men and women as was the case with the Gulf War. Negligible to minor adverse environmental impacts associated with the renovation phase and operation phase of the proposed action would be eliminated, but the needs of the national defense would not be best served by this alternative.

6.0 CONCLUSIONS

The principal conclusions of this EA are: (1) risks to the environment and human health and safety associated with implementing the proposed action are extremely small; (2) renovation and expansion of existing MBPI anthrax vaccine production facilities will have negligible adverse environmental impacts; and therefore, (3) implementation of the proposed action will not result in significant adverse environmental impacts and will result in significant benefits to the national defense posture. Implementation of Alternative II (Meeting Increased Anthrax Vaccine Production Needs through a Source Other than MBPI) or Alternative III (No Action Alternative) does not adequately address the needs of the national defense.

Alternative II, which involves transferring anthrax vaccine production and testing activities to another location, will cause a significant delay in meeting identified needs with respect to biological defense as identified by the DoD. Further, continuing current MBPI anthrax vaccine production and testing activities in existing facilities and in their present size and scope (Alternative III) will not meet the needs of national defense because existing facilities at MBPI are inadequate to accommodate increased production of anthrax vaccine. Implementation of either alternative is not likely to cause significant adverse environmental impacts.

The renovation and expansion of anthrax vaccine production and testing facilities at MBPI, as well as operation of these facilities, are likely to be performed without significant environmental impact. The most severe potential effects associated with the proposed action are predicted to be minor, and to date, all observed effects at this site have been insignificant. Potential risks to MBPI production and testing employees, public health, and the environment will continue to be mitigated by the application of required work practice and engineering controls that direct the safe handling, use, and disposal of potentially infectious or potentially hazardous materials. Implementation of the proposed action (Alternative I) will result in significant benefits to the national defense posture.

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8.0 PERSONS AND AGENCIES CONSULTED

Individual, Affiliation, Telephone

Craig Anderson, Tri-County Planning Commission, (517) 393-0342

Dr. George Burgoyne, Michigan Biologic Products Institute, (517) 335-8094

Jane Bush, Michigan State Historic Preservation Office, (517) 335-2721

Dr. Robert Carton, USAMRMC, Environmental Coordinator, (301) 619-2004

Louise Christian, Lansing Planning Division, (517) 483-4066

Kenneth Damrel, Michigan Department of Environmental Quality, (517) 625-4663

Arthur Davis, Michigan Department of Public Health, (517) 335-8094

Kathryn Eckert, Michigan State Historic Preservation Office, (517) 335-2721

Scott Hanshue, Department of Environmental Quality, (517) 335-1125

Dr. David Johnson, MDPH Public Affairs Department, (517) 373-0408

Bill Kaiser, City of Lansing Wastewater Treatment Plant, (517) 483-4404

Kristine Kidorf, Michigan State Historic Preservation Office, (517) 373-1630

Dr. Barbara Kintner, Michigan Biologic Products Institute, (517) 335-8094

LTC Ross LeClaire, USAMRMC, COR, (301) 619-4260

Larry Mattson, Michigan Department of Public Health, (517) 335-8094

George Mechem, Michigan Employment Security Agency, (517) 241-7286

Bill Nummy, Michigan Biologic Products Institute, (517) 335-8094

Bill Rieske, Lansing Planning Division, (517) 483-4091

Bob Rusch, DEQ Air Quality Division, (517) 373-7041

Lori G. Sargent, Michigan Department of Natural Resources, (517) 373-1263

Tom Schaeffer, Lansing Fire Marshal, (517) 483-4200

Liane Shekter Smith, Community Water Supply Section for the DEQ, (517) 335-9216

Nancy Summerton, Michigan Biologic Products Institute, (517) 335-8094

Thomas Weise, Michigan Department of Natural Resources, (517) 373-1263

Linda Williams, Michigan Department of Agriculture, (517) 373-9866

9.0 PREPARERS

The following personnel, under a USAMRMC contract to Science Applications International Corporation, provided instrumental technical assistance to the JPO BD in the preparation of this Environmental Assessment.

Preparers:

John R. Beaver
Ph.D., Environmental Engineering Sciences
BSA Environmental Services, Inc., Beachwood, OH

Nicole A. Ferrari
B.S., Biology
BSA Environmental Services, Inc., Beachwood, OH

Beth A. Schaberg
M.S., Biology
BSA Environmental Services, Inc., Beachwood, OH

Robin L. Phillips
M.S., Environmental Science
BSA Environmental Services, Inc., Beachwood, OH

10.0 ACRONYMS AND ABBREVIATIONS

AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
ABL	Animal Biosafety Level
AR	Army Regulation
BD	Biological Defense
BDRP	Biological Defense Research Program
BL	Biosafety Level
BMPs	Best Management Practices
CAA	Clean Air Act
CATA	Capital Area Transit Authority
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CEQ	Council on Environmental Quality
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
cfs	cubic feet per second
cGMP	current Good Manufacturing Practices
CHO	Chemical Hygiene Officer
CHP	Chemical Hygiene Plan
CO	carbon monoxide
CWA	Clean Water Act
DA	Department of the Army
DEQ	Department of Environmental Quality
DHHS	Department of Health and Human Services
DNR	Department of Natural Resources
DoD	Department of Defense
DoDD	Department of Defense Directive
DOT	Department of Transportation
EA	Environmental Assessment
EO	Executive Order
EOE	Equal Opportunity Employment
FDA	Food and Drug Administration
FNSI	Finding of No Significant Impact
FPEIS	Final Programmatic Environmental Impact Statement
GLP	Good Laboratory Practices
HAPs	Hazardous Air Pollutants
HEPA	High-efficiency particulate air
HVAC	Heating, ventilation and air conditioning
JCS	Joint Chiefs of Staff
JPO	Joint Program Office
JVAP	Joint Vaccine Acquisition Program
MBPI	Michigan Biologic Products Institute
MCE	Maximum Credible Event
MDPH	Michigan Department of Public Health
mgd	million gallons per day
MIOSHA	Michigan Occupational Safety and Health Act
MSDS	Material Safety Data Sheets

msl	mean sea level
NAAQS	National Ambient Air Quality Standards
NEPA	National Environmental Policy Act
NIH	National Institutes of Health
NOAA	National Oceanic and Atmospheric Administration
NO _x	nitrogen oxides
NPDES	National Pollutant Discharge Elimination System
NRC	National Research Council
OSHA	Occupational Safety and Health Administration
PAM	Pamphlet
Pb	Lead
PEA	Programmatic Environmental Assessment
PEL	Permissible Exposure Limits
RCRA	Resource Conservation and Recovery Act
RDT&E	Research, Development, Test and Evaluation
SDWA	Safe Drinking Water Act
SHPO	State Historic Preservation Office
SO ₂	sulfur dioxide
SOP	Standard Operating Procedure
TSI-GSD	The Salk Institute-Government Services Division
USAG	U.S. Army Garrison
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USAMRICD	U.S. Army Medical Research Institute of Chemical Defense
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	U.S. Code
USDA	U.S. Department of Agriculture
USEPA	U.S. Environmental Protection Agency
USFWS	U.S. Fish and Wildlife Service
VAERS	Vaccine Adverse Event Reporting System
VOCs	volatile organic compounds
WRAIR	Walter Reed Army Institute of Research
WWTP	Wastewater Treatment Plant

Appendix A

Chemical Inventory for Anthrax Vaccine Production and Testing Activities at MBPI as of February 18, 1997

Chemical	GMP#	Expiration Date	Seed Amount	Product Amount	4 sets x 50 runs/year	# of bottles in stock	Weight per bottle	Total amount on hand	Amount over or (short)
Formalin	1-4931	2-10-98	*	2.5 ml	500 ml	2	500 ml	1000 ml	500 ml
Phemerol	1-4648	12-13-97	*	.290 g	58 g	4	5 g	20 g	(38 g)
Adenosine	1-4907	1-14-99	.010 g	.100 g	22 g	9	5 g	45 g	23 g
L-Alanine	1-4908	12-30-98	.090 g	.900 g	198 g	9	100 g	900 g	702 g
Tryptophan	1-4630	10-27-97	.104 g	1.040 g	228.8 g	10	25 g	250 g	21.2 g
Serine	1-4643	12-12-97	.208 g	2.080 g	457.6 g	6	100 g	600 g	257.6 g
Arginine	1-4359	9-4-96	.208 g	2.080 g	457.6 g	5	25 g	125 g	
Arginine	1-4640	11-7-97	.208 g	2.080 g	457.6 g	5	100 g	500 g	167.4 g
Proline	1-4645	10-31-97	.292 g	2.920 g	642.4 g	6	100 g	600 g	(42.4 g)
Proline	1-4928	2-4-99	.292 g	2.920 g	642.4 g	5	100 g	500 g	457.6 g
Glycine	1-4267	4-30-98	.292 g	2.920 g	642.4 g	3	500 g	1500 g	857.6 g
Methionine	1-4647	11-2-97	.300 g	3.000 g	660 g	6	100 g	600 g	(60 g)
Methionine	1-4927	2-4-99	.300 g	3.000 g	660 g	5	100 g	500 g	440 g
Threonine	1-4642	11-7-97	.600 g	6.000 g	1320 g	6	100 g	600 g	(720 g)
Valine	1-4638	11-8-97	.600 g	6.000 g	1320 g	12	100 g	1200 g	(120 g)
Aspartic Acid	1-4635	11-6-97	.640 g	6.400 g	1408 g	12	100 g	1200 g	(208 g)
Isoleucine	1-4771	5-10-98	.640 g	6.400 g	1408 g	2	500 g	1000 g	(408 g)
Isoleucine	1-4858	9-26-98	.640 g	6.400 g	1408 g	5	100 g	500 g	108 g
Phenyl-alanine	1-4637	1-10-98	.680 g	6.800 g	1496 g	13	100 g	1300 g	(496 g)
Histidine	1-4649	10-31-96	.960 g	9.600 g	2112 g	11	100 g	1100 g	(1012 g)
Leucine	1-4629	10-27-97	1.260 g	12.600 g	2772 g	6	500 g	3000 g	228 g
Glutamic Acid	1-4636	11-3-97	1.680 g	16.800 g	3696 g	25	100 g	2500 g	(1196 g)
Sodium Bicarbonate	1-4489	4-12-2000	25 g	375 g	80000 g	1 left of six	2500 g	2500 g	(60000 g)

Chemical	GMP#	Expiration Date	Seed Amount	Product Amount	4 sets x 50 runs/year	# of bottles in stock	Weight per bottle	Total amount on hand	Amount over or (short)
Sodium Bicarbonate	1-4750	4-10-2001	25 g	375 g	80000 g	4	2500 g	10000g	(50000 g)
Biotin	1-4926	2-7-99	.005 g	.050 g	11 g	3	1 g	3 g	2 g
Biotin	1-4641	11-13-97	.005 g	.050 g	11 g	5	1 g	5 g	(1 g)
Thiamin	1-4628	1-8-98	.004 g	.040 g	8.8 g	4	10 g	40 g	31.2 g
Dextrose	1-4272	10-31-98	10 g	100 g	22000 g	1	500 g	500 g	*
Dextrose	1-4457	4-30-99	10 g	100 g	22000 g	25	500 g	12500	(9000 g)
HCL	1-4433	1-26-2000	0.3 ml	3.0 ml	660 ml	2	2500 ml	5000 ml	9340 ml
Sodium Chloride	1-4046	7-14-98	*	100 g	20000 g	4	3000 g	12000g	*
Sodium Chloride	1-4616	10-24-2000	*	100 g	20000 g	2	2500 g	5000 g	(3000 g)
Alhydrogel	1-4403	2-7-2000	*	1400 ml	280000 ml	123	1000 ml	123000 ml	(157000 ml)
Sodium Hydroxide	1-4608	10-8-97	*	~ 48 g	9600 g	6	2500 g	15000 g	5400 g
Sulfuric Acid	1-4399	12-7-99	*	250 ml	50000 ml	2	2500 ml	5000 ml	(42500 ml)
Nitric Acid				varies		2	2500 ml	5000 ml	as needed to clean tanks
Waste Acid from anthrone test				500 ml/week		4	2500 ml	10000 ml	sulfuric acid waste
Phenol				3.0 ml		2	500 ml	1000 ml	Used to make seed spore tubes
Manganese Sulfate	1-4639	11-7-2000	.040 g	.400 g	88 g	4	5 g	20 g	(68 g)
Manganese Sulfate	1-4809	8-2-2001	.040 g	.400 g	88 g	5	100 g	500 g	432 g
Magnesium Sulfate	1-4444	2-22-2000	.100 g	1,000 g	220 g	3	500 g	1500 g	1280 g

Chemical	GMP#	Expiration Date	Seed Amount	Product Amount	4 sets x 50 runs/year	# of bottles in stock	Weight per bottle	Total amount on hand	Amount over or (short)
Calcium Chloride	1-3802	5-1-97	.148 g	1,480 g	325.6 g	2	2500 g	5000 g	*
Calcium Chloride	1-4211	12-16-98	.148 g	1,480 g	325.6 g	2	500 g	1000 g	5674.4 g
Guanine	1-4631	10-26-97	.092 g	.920 g	202.4 g	10	25 g	250 g	47.6 g
Potassium Phosphate Monobasic	1-4552	6-28-2000	6,800 g	68,000 g	14960 g	8	500 g	4000 g	*
Potassium Phosphate Monobasic	1-4552	6-28-2000	6,800 g	68,000 g	14960 g	8	500 g	4000 g	(7960 g)
Potassium Phosphate Dibasic	1-4646	11-8-2000	8,700 g	87,000 g	19140 g	6	500 g	3000 g	*
Potassium Phosphate Dibasic	1-3702	1-28-97	8,700 g	87,000 g	19140 g	4	2500 g	10000 g	*
Potassium Phosphate Dibasic	1-4195	12-21-98	8,700 g	87,000 g	19140 g	3	500 g	1500 g	(4640 g)
Ferrous Sulfate	1-4362	10-6-99	.029 g	.290 g	63.8 g	5	250 g	1250 g	1186.2 g
Pyroxidine	1-4644	11-8-97	.010 g	.100 g	22 g	4	10 g	40 g	18 g
Ethanol				varies		3	1 gal.	3 gal.	General purpose disinfectant
Sodium Hypochlorite (Bleach)				varies		4	1 gal.	4 gal.	General disinfectant & sporicide
LPH				varies		1	1 gal.	1 gal.	Disinfectant
Environ				varies		1	1 gal.	1 gal.	Disinfectant
SporKlenze				varies		1	1 gal.	1 gal.	Sporicide

Chemical	GMP#	Expiration Date	Seed Amount	Product Amount	4 sets x 50 runs/year	# of bottles in stock	Weight per bottle	Total amount on hand	Amount over or (short)
C.I.P.				varies		1	20 L	20 L	Detergent/ Cleaner for fermenters & tanks, bulk storage container
GlassKlenze				varies		2	1 gal.	2 gal.	Glassware detergent
Isopropyl alcohol spray				varies		36	11 oz	396 oz.	Aerosol spray disinfectant
Anthrone				0.50 g		2	10 g	20 g	Color reagent for anthrone test

(Additional amounts of cleaners and alcohols may be stored in the outside storage room)

Appendix B



JOHN ENGLER, GOVERNOR

MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

ROBERT C. MYERS, D.V.M., DIRECTOR
3500 N. MARTIN LUTHER KING, JR., BLVD.
P.O. BOX 30035
LANSING, MICHIGAN 48909
TELEPHONE: (517) 335-8120
FAX: (517) 335-9486

MICHIGAN BIOLOGIC
PRODUCTS COMMISSION
DENNIS L. SCHORSACK, CHAIR
JAMES K. HAYMAN, JR.
MARY A. LANNOME

November 5, 1997

Joseph Little, Contracting Officer
U.S. Army Medical Research Acquisition Activity
Attention: MCMR-AAA-J
Fort Detrick
Frederick, MD 21702-5014

Dear Mr. Little,

The Michigan Biologic Products Institute (MBPI) produces vaccines for the Department of Defense. The research, development and testing of these products involve hazardous and lethal materials. MBPI has contacted the City of Lansing in an attempt to formalize a Memorandum of Agreement relative to the requirements of Title 10, United States Code, Section 2370, to ensure effective fire, police and health emergency support services.

The City of Lansing, Office of City Attorney, has provided MBPI with a copy (attached) of Ordinance #968, Chapter 234, which deals with the City's role in Emergency Management situations. The City officials have been advised of, and provided with, the CFR Part 626 regulations as well as Army Regulation 385-69. It is the position of the City of Lansing that all requirements of those regulations have been met by Ordinance #968.

MBPI will coordinate annually with the City of Lansing, Emergency Management Director, according to Ordinance #968, Chapter 234, regarding emergency response to incidents at the facility.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Tanner".

Michael A. Tanner
Chief Administrative Officer

cc: Dr. R Myers
E Maes
W Hall, City of Lansing
Dr. V Sanchez

ORDINANCE #968
CHAPTER 234
EMERGENCY MANAGEMENT

AN ORDINANCE OF THE CITY OF LANSING, MICHIGAN, TO CREATE A NEW CHAPTER 234 OF THE CODIFIED ORDINANCES OF THE CITY OF LANSING, MICHIGAN, FOR THE PURPOSE OF CREATING AN EMERGENCY MANAGEMENT ORDINANCE.

THE CITY OF LANSING ORDAINS:

SECTION 1. THAT A NEW CHAPTER 234 BE ADDED TO THE CODE OF ORDINANCES OF THE CITY OF LANSING, MICHIGAN, TO READ AS FOLLOWS:

CHAPTER 234: THIS ORDINANCE SHALL BE KNOWN AND MAY BE CITED AS THE "LANSING EMERGENCY MANAGEMENT ORDINANCE."

234.01 PURPOSE.

THE PURPOSE OF THIS CHAPTER IS TO PROVIDE FOR THE MITIGATION, PREPAREDNESS, RESPONSE AND RECOVERY FROM NATURAL AND HUMAN-MADE DISASTERS WITHIN THE CITY OF LANSING, MICHIGAN; TO ESTABLISH AN OFFICE FOR THIS PURPOSE; TO PROVIDE FOR THE COORDINATION AND UTILIZATION OF ALL RESOURCES IN THE MUNICIPALITY IN AN EMERGENCY OR DISASTER SITUATION; AND TO PROVIDE A MEANS THROUGH WHICH THE MAYOR AND THE CITY COUNCIL MAY EXERCISE THE AUTHORITY AND DISCHARGE THE RESPONSIBILITIES VESTED IN THEM BY THIS CHAPTER AND MICHIGAN COMPILED LAWS, SECTIONS 30.401 ET SEQ. OR ACT NO. 390 OF THE PUBLIC ACTS OF 1976, AS AMENDED.

234.02 DEFINITIONS.

AS USED IN THIS CHAPTER:

(A) "ACT" MEANS THE MICHIGAN EMERGENCY MANAGEMENT ACT, ACT NO. 390 OF THE PUBLIC ACTS OF 1976, AS AMENDED.

(B) "DISASTER" MEANS AN OCCURRENCE OR THREAT OF WIDESPREAD OR SEVERE DAMAGE, INJURY OR LOSS OF LIFE OR PROPERTY RESULTING FROM ANY NATURAL OR HUMAN-MADE CAUSE, INCLUDING BUT NOT LIMITED TO, FIRE, FLOOD, SNOWSTORM, ICE STORM, TORNADO, WINDSTORM, OIL SPILL, WATER CONTAMINATION, UTILITY FAILURE, HAZARDOUS PEACETIME RADIOLOGICAL INCIDENT, MAJOR TRANSPORTATION ACCIDENT, HAZARDOUS MATERIALS INCIDENT, EPIDEMIC, AIR CONTAMINATION, BLIGHT, DROUGHT, INFESTATION, EXPLOSION, OR HOSTILE MILITARY OR PARAMILITARY ACTION, OR SIMILAR OCCURRENCES RESULTING FROM TERRORIST ACTIVITIES, RIOTS, OR CIVIL DISORDERS.

(C) "DISTRICT COORDINATOR" MEANS THE MICHIGAN DEPARTMENT OF STATE POLICE DISTRICT EMERGENCY MANAGEMENT COORDINATOR. THE DISTRICT COORDINATOR SERVES AS LIAISON BETWEEN LOCAL EMERGENCY MANAGEMENT PROGRAMS AND THE MICHIGAN STATE POLICE, EMERGENCY MANAGEMENT DIVISION IN ALL MATTERS PERTAINING TO THE MITIGATION, PREPAREDNESS, RESPONSE AND RECOVERY OF

EMERGENCY AND DISASTER SITUATIONS

(D) "DISASTER RELIEF FORCE" MEANS ALL AGENCIES OF LANSING GOVERNMENT, PRIVATE AND VOLUNTEER PERSONNEL AND EQUIPMENT, PUBLIC OFFICERS AND EMPLOYEES, AND ALL OTHER PERSONS OR GROUPS OF PERSONS OR EQUIPMENT IDENTIFIED IN THE LANSING EMERGENCY OPERATIONS PLAN AS HAVING DUTIES TO PERFORM OR THOSE CALLED INTO DUTY OR WORKING AT THE DIRECTION OF A PARTY IDENTIFIED IN THE PLAN TO PERFORM A SPECIFIC DISASTER OR EMERGENCY RELATED TASK DURING A LOCAL STATE OF EMERGENCY OR DISASTER.

(E) "EMERGENCY" MEANS ANY SITUATION CONFRONTING THE CITY REQUIRING EMERGENCY ACTIONS OF A LESSER NATURE THAN A DISASTER TO INCLUDE, BUT NOT LIMITED TO, CIVIL DISTURBANCES, LABOR STRIKES, VISITS BY NATIONAL OR INTERNATIONAL DIGNITARIES, EVACUATIONS AND BUILD-UP ACTIVITIES PRIOR TO AN ACTUAL DISASTER.

(F) "EMERGENCY MANAGEMENT DIRECTOR" MEANS THE FIRE CHIEF WHO IS APPOINTED TO COORDINATE ALL MATTERS PERTAINING TO EMERGENCY MANAGEMENT WITHIN THE CITY.

(G) "EMERGENCY MANAGEMENT PROGRAM" MEANS A PROGRAM ESTABLISHED TO COORDINATE MITIGATION, PREPAREDNESS, RESPONSE AND RECOVERY ACTIVITIES FOR ALL EMERGENCY OR DISASTER SITUATIONS WITHIN A GIVEN GEOGRAPHIC AREA MADE UP OF ONE OR SEVERAL POLITICAL SUBDIVISIONS. SUCH A PROGRAM HAS AN APPOINTED EMERGENCY MANAGEMENT COORDINATOR/DIRECTOR AND MEETS THE PROGRAM STANDARDS AND REQUIREMENTS AS ESTABLISHED BY THE DEPARTMENT OF STATE POLICE, EMERGENCY MANAGEMENT DIVISION. THE CITY OF LANSING HAS ESTABLISHED AN EMERGENCY MANAGEMENT PROGRAM.

(H) "EMERGENCY MANAGEMENT PROGRAM MANAGER" MEANS THE PERSON ASSIGNED BY THE EMERGENCY MANAGEMENT DIRECTOR TO ASSIST IN ALL MATTERS PERTAINING TO EMERGENCY MANAGEMENT WITHIN THE CITY.

(I) "EMERGENCY OPERATIONS PLAN" MEANS THE PLAN DEVELOPED AND MAINTAINED BY THE CITY OF LANSING FOR THE PURPOSE OF RESPONDING TO ALL EMERGENCY OR DISASTER SITUATIONS BY IDENTIFYING AND ORGANIZING THE DISASTER RELIEF FORCE.

(J) "LOCAL STATE OF EMERGENCY" MEANS A DECLARATION BY THE MAYOR PURSUANT TO THE ACT AND THIS CHAPTER WHICH IMPLEMENTS THE RESPONSE AND RECOVERY ASPECTS OF THE CITY OF LANSING EMERGENCY OPERATIONS PLAN AND AUTHORIZES CERTAIN ACTIONS AS DESCRIBED IN THIS CHAPTER.

(K) "VITAL RECORDS" MEANS THOSE RECORDS THAT CONTAIN INFORMATION NEEDED TO CONTINUE THE EFFECTIVE FUNCTIONING OF THE CITY OF LANSING AND DEPARTMENTS AND FOR THE PROTECTION OF THE RIGHTS AND INTERESTS OF PERSONS UNDER EMERGENCY CONDITIONS IN THE EVENT OF AN EMERGENCY OR DISASTER SITUATION.

234.03 EMERGENCY MANAGEMENT OFFICE; EMERGENCY MANAGEMENT DIRECTOR

THERE IS ESTABLISHED AN OFFICE OF EMERGENCY MANAGEMENT WITHIN THE LANSING FIRE DEPARTMENT FOR THE PURPOSE OF COORDINATING ALL EMERGENCY AND DISASTER MITIGATION, PREPAREDNESS, RESPONSE AND RECOVERY ACTIVITIES WITHIN THE CITY. IT SHALL BE STAFFED BY AN EMERGENCY MANAGEMENT PROGRAM MANAGER AND SUCH OTHER ASSISTANTS NECESSARY FOR THE PROPER FUNCTIONING OF THE OFFICE. THE FIRE CHIEF, APPOINTED BY THE MAYOR AS THE EMERGENCY MANAGEMENT DIRECTOR, SHALL HAVE RESPONSIBILITY FOR THE ORGANIZATION, ADMINISTRATION, AND OPERATION OF THE OFFICE, SUBJECT TO THE DIRECTION AND CONTROL OF THE MAYOR.

(A) THE MAYOR SHALL ALSO DESIGNATE A MINIMUM OF TWO PERSONS AS SUCCESSORS TO THE POSITION OF EMERGENCY MANAGEMENT DIRECTOR. THE LINE OF SUCCESSION SHALL BE LISTED IN THE EMERGENCY OPERATIONS PLAN.

234.04 EMERGENCY MANAGEMENT DIRECTOR; DUTIES.

(A) THE EMERGENCY MANAGEMENT DIRECTOR SHALL ACT FOR AND AT THE DIRECTION OF THE MAYOR IN THE COORDINATION OF ACTIVITIES DURING TIMES OF MAJOR EMERGENCIES AND DISASTERS.

(B) THE EMERGENCY MANAGEMENT DIRECTOR ASSISTED BY THE EMERGENCY MANAGEMENT PROGRAM MANAGER SHALL COMPLY WITH THE STANDARDS AND REQUIREMENTS AS ESTABLISHED BY THE DEPARTMENT OF STATE POLICE, EMERGENCY MANAGEMENT DIVISION, UNDER THE AUTHORITY OF THE ACT IN ACCOMPLISHING THE FOLLOWING:

- (1) DIRECT AND COORDINATE THE DEVELOPMENT OF THE CITY OF LANSING EMERGENCY OPERATIONS PLAN, WHICH SHALL BE CONSISTENT IN CONTENT WITH THE MICHIGAN EMERGENCY MANAGEMENT PLAN.
- (2) SPECIFY DEPARTMENTS OR AGENCIES WHICH MUST PROVIDE AN ANNEX TO THE PLAN OR OTHERWISE COOPERATE IN ITS DEVELOPMENT.
- (3) IDENTIFY DEPARTMENTS AND AGENCIES TO BE INCLUDED IN THE EMERGENCY OPERATIONS PLAN AS THE DISASTER RELIEF FORCE.
- (4) COORDINATE THE DEVELOPMENT AND MAINTENANCE OF A CITY RESOURCE MANUAL.
- (5) COORDINATE THE RECRUITMENT AND UTILIZATION OF VOLUNTEER PERSONNEL AND AGENCIES TO AUGMENT CITY RESOURCES FOR EMERGENCY MANAGEMENT PURPOSES.
- (6) ASSURE THE EMERGENCY MANAGEMENT PROGRAM MEETS ELIGIBILITY REQUIREMENTS FOR STATE AND FEDERAL AID.
- (7) COORDINATE AND/OR CONDUCT TRAINING AND EXERCISE PROGRAMS FOR THE DISASTER RELIEF FORCE WITHIN THE CITY AND TO TEST THE ADEQUACY OF THE EMERGENCY OPERATIONS PLAN.
- (8) THROUGH PUBLIC INFORMATION PROGRAMS, EDUCATE THE POPULATION AS TO ACTIONS NECESSARY FOR THE PROTECTION OF LIFE AND PROPERTY IN AN EMERGENCY OR DISASTER.
- (9) ASSIST IN THE DEVELOPMENT OF MUTUAL AID AGREEMENTS, WHICH MAY BE REVIEWED BY CITY COUNCIL.
- (10) OVERSEE THE IMPLEMENTATION OF ALL FUNCTIONS NECESSARY DURING AN EMERGENCY OR DISASTER IN ACCORDANCE WITH THE EMERGENCY

OPERATIONS PLAN.

- (1 1) COORDINATE CITY EMERGENCY MANAGEMENT ACTIVITIES WITH THOSE OF THE COUNTY, STATE AND ADJACENT JURISDICTIONS.
 - (1 2) COORDINATE ALL EMERGENCY PREPAREDNESS ACTIVITIES, INCLUDING MAINTAINING PRIMARY AND ALTERNATE EMERGENCY OPERATIONS CENTERS.
 - (1 3) IDENTIFY MITIGATION OPPORTUNITIES WITHIN THE CITY AND ENCOURAGE DEPARTMENTS/AGENCIES TO IMPLEMENT MITIGATION MEASURES.
- (B) THE EMERGENCY MANAGEMENT DIRECTOR SHALL SUPERVISE THE ACTIVITIES OF THE EMERGENCY MANAGEMENT OFFICE ON A CONTINUOUS BASIS. WITH THE ADVICE AND CONSENT OF THE MAYOR, HE/SHE SHALL FORMULATE, REVIEW AND APPROVE POLICY AND OPERATIONAL GUIDELINES FOR THIS OFFICE AS NEEDED.

234.05 MAYOR: POWERS; DUTIES.

(A) WHEN CIRCUMSTANCES WITHIN THE CITY INDICATE THAT THE OCCURRENCE OR THREAT OF OCCURRENCE OF WIDESPREAD OR SEVERE DAMAGE, INJURY OR LOSS OF LIFE OR PROPERTY EXISTS, THE MAYOR MAY DECLARE A LOCAL STATE OF EMERGENCY. SUCH A DECLARATION SHALL BE PROMPTLY FILED WITH THE DEPARTMENT OF STATE POLICE, EMERGENCY MANAGEMENT DIVISION. THIS DECLARATION SHALL NOT BE CONTINUED OR RENEWED FOR A PERIOD IN EXCESS OF 7 DAYS EXCEPT WITH THE CONSENT OF THE CITY COUNCIL.

(B) IF THE MAYOR INVOKES SUCH POWER AND AUTHORITY, HE/SHE SHALL, AS SOON AS REASONABLY EXPEDIENT, CONVENE THE CITY COUNCIL FOR ONE OR MORE EMERGENCY MEETINGS IN ACCORDANCE WITH THE OPEN MEETINGS ACT TO PERFORM ITS NORMAL LEGISLATIVE AND ADMINISTRATIVE DUTIES AS THE SITUATION DEMANDS, AND WILL REPORT TO THAT BODY RELATIVE TO EMERGENCY ACTIVITIES. NOTHING IN THIS ORDINANCE SHALL BE CONSTRUED AS ABRIDGING OR CURTAILING THE POWERS OF THE CITY COUNCIL UNLESS SPECIFICALLY PROVIDED HEREIN.

(C) THE MAYOR MAY DO ONE OR MORE OF THE FOLLOWING UNDER A LOCAL STATE OF EMERGENCY:

- (1) DIRECT THE EMERGENCY MANAGEMENT DIRECTOR TO IMPLEMENT THE EMERGENCY OPERATIONS PLAN.
- (2) ISSUE DIRECTIVES AS TO TRAVEL RESTRICTIONS ON LOCAL ROADS WITHIN THE CITY.
- (3) RELIEVE CITY EMPLOYEES OF NORMAL DUTIES AND TEMPORARILY REASSIGN THEM TO OTHER DUTIES.
- (4) ACTIVATE MUTUAL AID AGREEMENTS.
- (5) DIRECT THE OVERALL DISASTER RELIEF EFFORT, INCLUDING THE DISASTER RELIEF FORCE, IN ACCORDANCE WITH THE EMERGENCY OPERATIONS PLAN.
- (6) NOTIFY THE PUBLIC AND RECOMMEND IN-PLACE SHELTER OR EVACUATION PROTECTIVE MEASURES.
- (7) REQUEST A STATE OF DISASTER OR EMERGENCY DECLARATION FROM THE GOVERNOR AS DESCRIBED IN 234.06.
- (8) WHEN OBTAINING NORMAL APPROVALS WOULD RESULT IN FURTHER INJURY OR DAMAGE, THE MAYOR MAY, UNTIL THE CITY COUNCIL CONVENES, WAIVE

PROCEDURES AND FORMALITIES OTHERWISE REQUIRED PERTAINING TO THE FOLLOWING:

- A. FOR A PERIOD OF UP TO 7 DAYS, SEND THE DISASTER RELIEF FORCE AND RESOURCES TO THE AID OF OTHER COMMUNITIES AS PROVIDED BY MUTUAL AID AGREEMENTS.
- B. FOR A PERIOD OF UP TO 7 DAYS APPROPRIATE AND EXPEND FUNDS.
- C. FOR A PERIOD OF UP TO 7 DAYS MAKE CONTRACTS, OBTAIN AND DISTRIBUTE EQUIPMENT, MATERIALS, AND SUPPLIES FOR DISASTER PURPOSES.
- D. EMPLOY TEMPORARY WORKERS.
- E. PURCHASE AND DISTRIBUTE SUPPLIES, MATERIALS, AND EQUIPMENT.
- F. MAKE, AMEND, OR RESCIND ORDINANCES OR RULES NECESSARY FOR EMERGENCY MANAGEMENT PURPOSES WHICH SUPPLEMENT A RULE, ORDER OR DIRECTIVE ISSUED BY THE GOVERNOR OR A STATE AGENCY. SUCH AN ORDINANCE OR RULE SHALL BE TEMPORARY AND, UPON THE GOVERNOR'S DECLARATION THAT A STATE OF DISASTER OR STATE OF EMERGENCY IS TERMINATED, SHALL NO LONGER BE IN EFFECT.

(D) IF A STATE OF DISASTER OR EMERGENCY IS DECLARED BY THE GOVERNOR, ASSIGN AND MAKE AVAILABLE FOR DUTY THE EMPLOYEES, PROPERTY, OR EQUIPMENT OF THE CITY WITHIN OR WITHOUT THE PHYSICAL LIMITS OF THE CITY AS ORDERED BY THE GOVERNOR OR THE DIRECTOR OF THE MICHIGAN DEPARTMENT OF STATE POLICE IN ACCORDANCE WITH THE ACT.

234.06 GOVERNOR DECLARATION REQUEST.

(A) IF A DISASTER OR EMERGENCY OCCURS THAT HAS NOT YET BEEN DECLARED TO BE A STATE OF DISASTER OR STATE OF EMERGENCY BY THE GOVERNOR, AND THE MAYOR DETERMINES THAT THE SITUATION IS BEYOND THE CONTROL OF THE MUNICIPALITY, HE/SHE MAY REQUEST THE GOVERNOR TO DECLARE THAT A STATE OF DISASTER OR STATE OF EMERGENCY EXISTS IN THE MUNICIPALITY. THE EMERGENCY MANAGEMENT DIRECTOR SHALL IMMEDIATELY CONTACT THE DISTRICT COORDINATOR. THE DISTRICT COORDINATOR, IN CONJUNCTION WITH THE EMERGENCY MANAGEMENT DIRECTOR, SHALL ASSESS THE NATURE AND SCOPE OF DISASTER OR EMERGENCY AND THEY SHALL RECOMMEND THE STATE PERSONNEL, SERVICES, AND EQUIPMENT THAT WILL BE REQUIRED FOR ITS PREVENTION, MITIGATION, OR RELIEF.

234.07 MUNICIPAL DEPARTMENTS; LIAISON; DUTIES.

(A) EACH DEPARTMENT/AGENCY OF CITY GOVERNMENT IDENTIFIED BY THE EMERGENCY MANAGEMENT DIRECTOR SHALL APPOINT AN EMERGENCY MANAGEMENT LIAISON WHO SHALL COORDINATE THE EMERGENCY MANAGEMENT ACTIVITIES OF THE DEPARTMENT/AGENCY AND ACT AS A LIAISON BETWEEN HIS/HER DEPARTMENT OR AGENCY AND THE EMERGENCY MANAGEMENT OFFICE ON ALL MATTERS PERTAINING TO EMERGENCY MANAGEMENT.

(B) EACH DEPARTMENT IDENTIFIED SHALL APPOINT A MINIMUM OF TWO PEOPLE TO SERVE AS SUCCESSORS IN THE EVENT THE EMERGENCY MANAGEMENT LIAISON IS NOT AVAILABLE OR REQUIRES ASSISTANCE. SUCCESSORS SHALL BE LISTED IN THE APPROPRIATE ANNEX TO THE EMERGENCY OPERATIONS PLAN.

(C) EACH DEPARTMENT LIAISON SHALL BE RESPONSIBLE FOR THE FOLLOWING:

- (1) PREPARE AND CONTINUOUSLY UPDATE AN ANNEX TO THE CITY OF LANSING EMERGENCY OPERATIONS PLAN PROVIDING FOR THE DELIVERY OF EMERGENCY MANAGEMENT ACTIVITIES BY THAT AGENCY OR DEPARTMENT. THE ANNEX SHALL BE IN THE FORM PRESCRIBED BY THE EMERGENCY MANAGEMENT DIRECTOR.
- (2) RECRUIT, APPOINT, AND ORGANIZE PRIVATE, VOLUNTEER AND OTHER PERSONNEL TO BE PART OF THE DISASTER RELIEF FORCE TO PERFORM SPECIFIC DUTIES AS ASSIGNED IN THE EMERGENCY OPERATIONS PLAN.
- (3) COORDINATE THE AGENCY'S OR DEPARTMENT'S EMERGENCY MANAGEMENT EFFORTS WITH THOSE OF OTHER AGENCIES.
- (4) ATTEND TRAINING COURSES RELEVANT TO THE FUNCTION OF THE AGENCY OR DEPARTMENT. AND ENSURE STAFF IS TRAINED SO AS TO BE ABLE TO IMPLEMENT ASSIGNED EMERGENCY FUNCTIONS.
- (5) PARTICIPATE IN PERIODIC EXERCISES TO ENHANCE THE ADEQUACY OF THE RESPECTIVE AGENCY'S OR DEPARTMENT'S RESPONSE CAPABILITY.
- (6) DEVELOP INTERNAL STANDARD OPERATING GUIDELINES TO ACCOMPLISH EMERGENCY NOTIFICATION AND ASSIGNED EMERGENCY TASKS.
- (7) PROVIDE THE EMERGENCY MANAGEMENT DIRECTOR WITH A LIST OF PERSONNEL AND RESOURCES AVAILABLE WITHIN THE AGENCY OR DEPARTMENT AND PROVIDE A LIST OF THOSE WHICH MAY BE NEEDED BY THE DEPARTMENT DURING TIMES OF EMERGENCY.
- (8) IDENTIFY AND PROVIDE FOR THE PROTECTION OF VITAL RECORDS.
- (9) IMPLEMENT THE DIRECTIVES OF THE MAYOR OR HIS/HER DESIGNEE UNDER A LOCAL STATE OF EMERGENCY.

234.08 VOLUNTEERS; APPOINTMENT.

(A) EACH MUNICIPAL DEPARTMENT, COMMISSION, BOARD, OR OTHER AGENCY OF MUNICIPAL GOVERNMENT IS AUTHORIZED TO APPOINT VOLUNTEERS TO AUGMENT ITS PERSONNEL IN TIME OF EMERGENCY TO IMPLEMENT EMERGENCY FUNCTIONS ASSIGNED IN THE EMERGENCY OPERATIONS PLAN. SUCH INDIVIDUALS ARE PART OF THE DISASTER RELIEF FORCE AND SHALL BE SUBJECT TO THE RULES AND OPERATIONAL CONTROL SET FORTH BY THE RESPECTIVE DEPARTMENT, COMMISSION, BOARD, OR AGENCY THROUGH WHICH THE APPOINTMENT WAS MADE, AND MAY BE REIMBURSED FOR ALL ACTUAL AND NECESSARY TRAVEL AND SUBSISTENCE EXPENSES.

234.09 RIGHTS OF DISASTER RELIEF FORCE

(A) IN ACCORDANCE WITH THE ACT, PERSONNEL OF THE DISASTER RELIEF FORCE WHILE ON DUTY SHALL HAVE THE FOLLOWING RIGHTS:

- (1) IF THEY ARE EMPLOYEES OF THE MUNICIPALITY, OR OTHER GOVERNMENTAL AGENCY REGARDLESS OF WHERE SERVING, HAVE THE POWERS, DUTIES,

RIGHTS, PRIVILEGES, AND IMMUNITIES AND RECEIVE THE COMPENSATION INCIDENTAL TO THEIR EMPLOYMENT.

- (2) IF THEY ARE NOT EMPLOYEES OF THE MUNICIPALITY OR OTHER GOVERNMENTAL AGENCY, BE ENTITLED TO THE SAME RIGHTS AND IMMUNITIES AS ARE PROVIDED FOR BY LAW.

234.10 TEMPORARY SEAT OF GOVERNMENT.

(A) THE MAYOR SHALL PROVIDE FOR THE TEMPORARY MOVEMENT AND REESTABLISHMENT OF ESSENTIAL GOVERNMENT OFFICES IN THE EVENT THAT EXISTING FACILITIES CANNOT BE USED.

234.11 LIABILITY.

(A) AS PROVIDED FOR IN THE ACT AND THIS ORDINANCE, THE MUNICIPALITY, OR THE AGENTS OR REPRESENTATIVES OF THE MUNICIPALITY, SHALL NOT BE LIABLE FOR PERSONAL INJURY OR PROPERTY DAMAGE SUSTAINED BY THE DISASTER RELIEF FORCE. IN ADDITION, ANY MEMBER OF THE DISASTER RELIEF FORCE ENGAGED IN DISASTER RELIEF ACTIVITY SHALL NOT BE LIABLE IN A CIVIL ACTION FOR DAMAGES RESULTING FROM AN ACT OR OMISSION ARISING OUT OF AND IN THE COURSE OF THE PERSON'S GOOD FAITH RENDERING OF THAT ACTIVITY, UNLESS THE PERSON'S ACT OR OMISSION WAS THE RESULT OF THAT PERSON'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT. THE RIGHT OF A PERSON TO RECEIVE BENEFITS OR COMPENSATION TO WHICH HE/SHE MAY OTHERWISE BE ENTITLED TO UNDER THE WORKER'S COMPENSATION LAW, ANY PENSION LAW, OR ACT OF CONGRESS WILL NOT BE EFFECTED AS A RESULT OF SAID ACTIVITY.

(B) AS PROVIDED FOR IN THE ACT, ANY PERSON OWNING OR CONTROLLING REAL ESTATE OR OTHER PREMISES WHO VOLUNTARILY AND WITHOUT COMPENSATION GRANTS THE MUNICIPALITY THE RIGHT TO INSPECT, DESIGNATE AND USE THE WHOLE OR ANY PART OF SUCH REAL ESTATE OR PREMISES FOR THE PURPOSE OF SHELTERING PERSONS OR FOR ANY OTHER DISASTER RELATED FUNCTION DURING A DECLARED LOCAL STATE OF EMERGENCY OR DURING AN AUTHORIZED PRACTICE DISASTER EXERCISE, SHALL NOT BE CIVILLY LIABLE FOR THE DEATH OF, OR INJURY TO, ANY PERSON ON OR ABOUT SUCH REAL ESTATE OR PREMISES UNDER SUCH LICENSE, PRIVILEGE OR OTHER PERMISSION, OR FOR LOSS OF, OR DAMAGE TO, THE PROPERTY OF SUCH PERSON.

SECTION 2. ALL ORDINANCES, RESOLUTIONS OR RULES, PARTS OF ORDINANCES, RESOLUTIONS OR RULES INCONSISTENT WITH THESE PROVISIONS ARE REPEALED.

SECTION 3. SHOULD ANY SECTION, CLAUSE OR PHRASE OF THIS ORDINANCE BE DECLARED TO BE INVALID, THE SAME SHALL NOT AFFECT THE VALIDITY OF THE ORDINANCE AS A WHOLE, OR ANY PART OTHER THAN THE PART SO DECLARED TO BE INVALID.

SECTION 4. THIS ORDINANCE SHALL TAKE EFFECT ON THE 30TH DAY AFTER ENACTMENT UNLESS GIVEN IMMEDIATE EFFECT BY THE CITY COUNCIL.

MARILYNN SLADE, CITY CLERK

Appendix C

Ingham County Element List

January 14, 1997

TYPE	SCIENTIFIC NAME	COMMON NAME	FEDERAL STATUS	STATE STATUS
A	<i>Accipiter cooperii</i>	Cooper's hawk		SC
A	<i>Acris crepitans blanchardi</i>	Blanchard's cricket frog		SC
P	<i>Angelica venenosa</i>	Hairy angelica		SC
P	<i>Arabis perstellata</i> var <i>shortii</i>	Rock cress		T
P	<i>Astragalus neglectus</i>	Cooper's milk-vetch		SC
P	<i>Baptisia lactea</i>	White or prairie false indigo		T
P	<i>Carex crux-cori</i>	Raven's-foot sedge		T
P	<i>Carex davisii</i>	Davis's sedge		SC
P	<i>Carex decomposita</i>	Log sedge		X
P	<i>Carex trichocarpa</i>	Hairy-fruited sedge		SC
P	<i>Carex typhina</i>	Cattail sedge		T
P	<i>Carya laciniosa</i>	Shellbark or kingnut hickory		SC
O	Champion tree	Pignut hickory (<i>carya glabra</i>)		
A	<i>Clemmys guttata</i>	Spotted turtle		SC
A	<i>Clemmys insculpta</i>	Wood turtle		SC
A	<i>Cryptotis parva</i>	Least shrew		T
P	<i>Diarrhena americana</i>	Beak grass		T
A	<i>Emydoidea blandingii</i>	Blanding's turtle		SC
G	Esker	Geographical feature		
I	<i>Gomphus lineatifrons</i>	White-lined clubtail		SC
O	Great blue heron rookery	Great blue heron rookery		
P	<i>Gymnocladus dioica</i>	Kentucky coffee-tree		SC
P	<i>Hemicarpha micrantha</i>	Dwarf-bulrush		SC
P	<i>Hieracium paniculatum</i>	Panicled hawkweed		SC
P	<i>Hybanthus concolor</i>	Green violet		SC
P	<i>Hydrastis canadensis</i>	Goldenseal		T
P	<i>Jeffersonia diphylla</i>	Twinleaf		SC
P	<i>Juncus biflorus</i>	Two-flowered rush		SC
P	<i>Linum virginianum</i>	Virginia flax		T
P	<i>Lycopus virginicus</i>	Virginia water-horehound		T
C	Mesic southern forest	Rich forest, central midwest type		
A	<i>Microtus pinetorum</i>	Woodland vole		SC
P	<i>Morus rubra</i>	Red mulberry		SC
A	<i>Moxostoma duquesnei</i>	Black redbreast		SC
A	<i>Moxostoma valenciennesi</i>	Greater redbreast		SC
A	<i>Myotis sodalis</i>	Indiana bat or indiana myotis	LE	E
A	<i>Notropis anogenus</i>	Pugnose shiner		SC
A	<i>Notropis texanus</i>	Weed shiner		E
P	<i>Panax quinquefolius</i>	Ginseng		T
I	<i>Papaipema speciosissima</i>	Regal fern borer		SC
P	<i>Platanthera ciliaris</i>	Orange or yellow fringed orchid		T

TYPE CODES: A = Vertebrate Animal; C = Plant Community; G = Geological Feature; I = Invertebrate Animal; N = Nonvascular Plant; O = Other Feature (e.g., Champion Tree, Rookery); P = Vascular Plant.

STATUS CODES: E or LE = Endangered; T or LT = Threatened; SC = Special Concern (rare, may become E or T in future); Px = Proposed Status; XN = Nonessential Experimental Population; X = Probably Extirpated. The combined status, LELT, indicates that the element is listed as endangered in part of its range and threatened in the rest of its range. The combined status, LTNL, indicates that the element is listed as threatened in part of its range and not listed in the rest of its range.



Michigan Natural Features Inventory
Stevens T. Mason Building
P.O. Box 30444
Lansing, MI 48909-7944
Phone: 517/373-1552 Fax: 517/373-6705

P	<i>Poa paludigena</i>	Bog bluegrass	T
A	<i>Rallus elegans</i>	King rail	E
P	<i>Rudbeckia fulgida</i> var <i>sullivantii</i>	Showy coneflower	SC
P	<i>Scirpus clintonii</i>	Clinton's bulrush	T
P	<i>Scirpus torreyi</i>	Torrey's bulrush	SC
P	<i>Scleria triglomerata</i>	Tall nut-rush	SC
P	<i>Scutellaria parvula</i>	Small skullcap	T
P	<i>Silene virginica</i>	Fire pink	T
P	<i>Silphium perfoliatum</i>	Cup-plant	T
A	<i>Sistrurus catenatus catenatus</i>	Eastern massasauga	SC
A	<i>Terrapene carolina carolina</i>	Eastern box turtle	SC
P	<i>Tradescantia virginiana</i>	Virginia spiderwort	SC

TYPE CODES: A = Vertebrate Animal; C = Plant Community; G = Geological Feature; I = Invertebrate Animal; N = Nonvascular Plant; C = Other Feature (e.g., Champion Tree, Rookery); P = Vascular Plant.

STATUS CODES: E or LE = Endangered; T or LT = Threatened; SC = Special Concern (rare, may become E or T in future); Px = Proposed Status; XN = Nonessential Experimental Population; X = Probably Extirpated. The combined status, LE/T, indicates that the element is listed as endangered in part of its range and threatened in the rest of its range. The combined status, LT/NL, indicates that the element is listed as threatened in part of its range and not listed in the rest of its range.



Michigan Natural Features Inventory
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Appendix D

Recipients of the EA

U.S. Senators

Honorable Carl Levin
SR-459 Russell Senate Office Building
U.S. Senate
Washington, DC 20510

Honorable Spencer Abraham
329 Dirksen Senate Office Building
Washington, DC 20510

State Senator

Honorable Dianne Byrum
Michigan Senate
410 Farnum Bldg.
P.O. Box 30036
Lansing, MI 48909-7536

U.S. Representative

Honorable Debbie Stabenow
House of Representatives
1516 Longworth House Office Building
Washington, DC 20515

State Representative

Honorable Lynne Martinez
Michigan House of Representatives
560 Roosevelt Building
Lansing, MI 48909

Michigan Executive Officials

Honorable John Engler
Governor of Michigan
111 South Capitol Street
Lansing, MI 48933

Michigan Department of Natural Resources
Executive Offices
Steven T. Mason Building, 7th Floor
Lansing, MI 48933

Michigan Department of Transportation
425 West Ottawa Street
P.O. Box 30050
Lansing, MI 48909

Michigan Department of Environmental Quality
Hollister Bldg., Box 30473
Lansing, MI 48909-7973

Ms. Mary Lannoye
Michigan Biologic Products Institute Commissioner
Department of Management and Budget
Lewis Cass Building, 1st Floor
320 South Walnut Street
Lansing, MI 48913

Mr. James Haveman, Jr.
Michigan Biologic Products Institute Commissioner
Director, Department of Community Health
Lewis Cass Building
320 South Walnut Street
Lansing, MI 48913

Mr. Dennis L. Schornack
Chairman, Michigan Biologic Products Institute Commission
George Romney Building, 3rd Floor
111 South Capitol
Lansing, MI 48933

Federal Government

U.S. Environmental Protection Agency
Region 5
77 West Jackson Blvd.
Chicago, IL 60604-3590

Michigan State Legislative Officials

Honorable David Hollister
Mayor of Lansing
124 West Michigan Avenue
Lansing, MI 48933-1605

Public Interest Groups

Mr. Jeremy Rifkin
Foundation on Economic Trends
1660 L Street, Suite 216
Washington, DC 20036

Planning and Neighborhood Development
119 Washington Square
Lansing, MI 48933

Honorable Mark Grebner
Chairperson, Ingham County Board of Commissioners
P.O. Box 319
Mason, MI 48854

Libraries

Lansing Public Library
401 South Capitol Avenue
Lansing, MI 48933

Ingham County Library
4538 Elizabeth Road
Lansing, MI 48917

Library of Michigan
717 Allegan
P.O. Box 30007
Lansing, MI 48909

Appendix E

NOTICE OF AVAILABILITY

RENOVATION OF FACILITIES AND INCREASED ANTHRAX VACCINE PRODUCTION AND TESTING AT THE MICHIGAN BIOLOGIC PRODUCTS INSTITUTE

The U.S. Department of the Army announces the availability for public review and comment of a draft Environmental Assessment (dEA) for the Renovation of Facilities and Increased Anthrax Vaccine Production and Testing at the Michigan Biologic Products Institute (MBPI) (formerly the Biologic Products Division of the Michigan Department of Public Health). The proposed action and subject of this dEA is expansion of anthrax vaccine production capabilities through the renovation of facilities located at the MBPI. As the only U.S. Food and Drug Administration licensed establishment for the production of anthrax vaccine, MBPI needs to increase its production capabilities of anthrax vaccine to implement U.S. government policy for protecting its armed forces against biological warfare agents. U.S. armed forces at risk can be immunized with the licensed anthrax vaccine. The Joint Program Office for Biological Defense (JPO BD) manages Department of Defense (DoD) vaccine development, production, and acquisition. JPO BD contracts with MBPI, through the U.S. Army Medical Research Acquisition Activity, to purchase anthrax vaccine for the DoD. The dEA systematically reviews the risks, issues and probable environmental consequences associated with the proposed action and the alternatives considered. The dEA concludes that the activities and alternatives analyzed would not have significant adverse effects upon the environment.

The Renovation of Facilities and Increased Anthrax Vaccine Production at the Michigan Biologic Products Institute dEA is available for public review and comment. Copies are available for review at the Ingham County Library, 4538 Elizabeth Rd., Lansing, MI 48917; Lansing Public Library, 401 South Capitol Avenue, Lansing, MI 48933-2037; and the Library of Michigan, 717 Allegan, P.O. Box 30007, Lansing, MI 48909.

A copy of the document may be obtained by writing to Joint Vaccine Acquisition Program Project Management Office, JVAP PMO (Attn: Mr. Bruce G. Kay), 568 Doughten Street, Fort Detrick, Maryland 21702-5040 or downloaded from the internet at <http://www.armymedicine.mil/jvap-mbpi-dea>.

Mr. Bruce G. Kay is the point of contact for requests for the dEA and documentation from previous environmental analyses referenced in the dEA. Written comments for consideration in preparing the final environmental assessment should be submitted to the same address and must be received no later than December 19, 1997.